

EXHIBIT A

Denise M. Elser, M.D.

Page 1

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC.) Master File No.
PELVIC REPAIR SYSTEM) 2:12-MD-02327
PRODUCTS LIABILITY) MDL 2327
LITIGATION)
_____) JOSEPH R. GOODWIN
) U.S. DISTRICT JUDGE
DIANNE M. BELLEW,)
)
Plaintiff,)
)
-vs-) No. 13-CV-22473
)
ETHICON, INC., ET AL.,)
)
Defendants.)
_____)

VIDEOTAPED DEPOSITION OF

DENISE M. ELSER, M.D.

September 16, 2014

Chicago, Illinois

Denise M. Elser, M.D.

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<p>1 The videotaped deposition of DENISE M. ELSER, M.D.,</p> <p>2 called by the Plaintiff for examination, taken</p> <p>3 pursuant to the Federal Rules of Civil Procedure of</p> <p>4 the United States District Courts pertaining to the</p> <p>5 taking of depositions, taken before CORINNE T.</p> <p>6 MARUT, C.S.R. No. 84-1968, Registered Professional</p> <p>7 Reporter and a Certified Shorthand Reporter of the</p> <p>8 State of Illinois, at the Park Hyatt Chicago, 800</p> <p>9 North Michigan Avenue, Chicago, Illinois, on</p> <p>10 September 16, 2014, commencing at 10:37 a.m.</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 I N D E X</p> <p>2 DENISE M. ELSER, M.D. EXAMINATION</p> <p>3</p> <p>4 BY MR. SLATER..... 6</p> <p>5 BY MR. COMBS..... 174</p> <p>6 BY MR. SLATER..... 202</p> <p>7 BY MR. COMBS..... 211</p> <p>8</p> <p>9 E X H I B I T S</p> <p>10 ELSER DEPOSITION EXHIBIT MARKED FOR ID</p> <p>11 No. 1 Expert Report of Denise Elser, 5</p> <p>12 M.D.</p> <p>13 No. 2 article, "Myofascial Pelvic 171</p> <p>14 Pain" by Spitznagle and</p> <p>15 Robinson</p> <p>16 No. 3 Gynecare Prolift IFU; Bates 176</p> <p>17 Nos. ETH.MESH.02341454 -</p> <p>18 02341459</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
Page 3	Page 5
<p>1 APPEARANCES:</p> <p>2 ON BEHALF OF THE PLAINTIFF (via videoconference):</p> <p>3 MAZIE SLATER KATZ & FREEMAN LLC</p> <p>4 103 Eisenhower Parkway, 2nd Floor</p> <p>5 Roseland, New Jersey 07068</p> <p>6 973-228-9898</p> <p>7 BY: ADAM M. SLATER, ESQ.</p> <p>8 aslater@mskf.net</p> <p>9</p> <p>10 ON BEHALF OF THE DEFENDANT ETHICON, INC.:</p> <p>11 THOMAS COMBS & SPANN PLLC</p> <p>12 300 Summers Street, Suite 1380</p> <p>13 Charleston, West Virginia 25301</p> <p>14 304-414-1800</p> <p>15 BY: PHILIP J. COMBS, ESQ.</p> <p>16 pcombs@tcspllc.com</p> <p>17</p> <p>18 -and-</p> <p>19</p> <p>20 BUTLER SNOW LLP</p> <p>21 1020 Highland Colony Parkway, Suite 1400</p> <p>22 Ridgeland, Missouri 39157</p> <p>23 601-948-5711</p> <p>24 BY: PAUL S. ROSENBLATT, ESQ.</p> <p>25 paul.rosenblatt@butlersnow.com</p> <p>VIDEOTAPED BY:</p> <p>MILO SAVICH</p> <p>REPORTED BY: CORINNE T. MARUT, C.S.R. No. 84-1968</p>	<p>1 (WHEREUPON, a certain document was</p> <p>2 marked Elser Deposition Exhibit</p> <p>3 No. 1, Expert Report of Denise</p> <p>4 Elser, M.D., for identification.)</p> <p>5 THE VIDEOGRAPHER: We are now on the record.</p> <p>6 My name is Milo Savich. I am a videographer for</p> <p>7 Golkow Technologies.</p> <p>8 Today's date is September 16, 2014 and</p> <p>9 the time is 10:37 a.m.</p> <p>10 This video deposition is being held in</p> <p>11 Chicago, Illinois in the matter of Dianne M. Bellew</p> <p>12 vs. Ethicon, Inc. et al., for the United States</p> <p>13 District Court, Southern District of West Virginia</p> <p>14 at Charleston.</p> <p>15 The deponent is Dr. Denise Elser.</p> <p>16 Will counsel please identify themselves</p> <p>17 for the record.</p> <p>18 MR. COMBS: Phil Combs and Paul Rosenblatt on</p> <p>19 behalf of the Defendants.</p> <p>20 MR. SLATER: Adam Slater for the Plaintiff.</p> <p>21 THE VIDEOGRAPHER: The Court Reporter is</p> <p>22 Corinne Marut who will now swear in the witness and</p> <p>23 we can proceed.</p> <p>24</p> <p>25</p>

2 (Pages 2 to 5)

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<p>1 (WHEREUPON, the witness was duly 2 sworn.) 3 DENISE M. ELSE, M.D., 4 called as a witness herein, having been first duly 5 sworn, was examined and testified as follows: 6 EXAMINATION 7 BY MR. SLATER: 8 Q. Good morning, Dr. Elser. 9 A. Good morning. 10 Q. I'm not sure if I heard you. Can you 11 just say something. Hello? 12 A. Hello, good morning. 13 Q. Okay. I hear you. Okay. 14 Dr. Elser, my name is Adam Slater. I'm 15 going to take your deposition now in the case. You 16 understand that's why we're here today? 17 A. Yes. 18 Q. I'm going to ask you questions and since 19 you're under oath, you understand you must tell the 20 truth, correct? 21 A. Yes. 22 Q. If I ask you a question that doesn't 23 make sense to you for some reason, just let me know 24 and I'll rephrase the question. Okay? 25 A. Okay.</p>	<p>1 discuss those facts that you felt were most 2 important to you in drawing the opinions that are 3 found in the report? 4 A. Yes. 5 Q. I'm sorry. What was the answer? 6 A. Yes. 7 Q. Okay. The report itself appears to go 8 to page 39 and then you have a list of literature 9 that begins after the report. Is that correct? 10 A. So, the literature list starts on 11 page 39. 12 Q. The list of literature that starts on 13 page 39 and goes through page 44, what is that 14 list? 15 A. These were references that I 16 specifically cited in the report. 17 Q. Is that the collection of literature 18 that you relied on in forming your opinions in this 19 case? 20 A. No, those were just ones from which I 21 took specific citations. 22 Q. In terms of your decision making in 23 writing your report, why did you cite those 24 articles in your report? 25 A. They may have contained certain figures</p>
Page 7	Page 9
<p>1 Q. Let's mark as Exhibit -- I think we 2 already did -- Elser 1, the report. Do we have 3 that there? 4 A. I have Exhibit 1. Elser 1. 5 Q. Dr. Elser, in front of you is what we've 6 marked as Exhibit Elser 1. Can you tell me what 7 that is? 8 A. It's the expert report that I prepared 9 in relation to this case. 10 Q. Do you know what date it is that you 11 completed this report? 12 A. Give me a second. I'm just looking for 13 the signature page, which I did not date. No, I 14 don't. I believe it was three or four weeks ago. 15 Q. That would be sometime in the middle of 16 August? 17 A. Correct. 18 Q. About? 19 A. That would be -- that would be my 20 estimate, correct. 21 Q. Does this report contain each of the 22 opinions that you've reached in this case? 23 A. To date, yes. 24 Q. In this report you go through various 25 facts and you discuss various facts. Did you</p>	<p>1 or facts that I wanted to stress, but those are not 2 the only articles I've read on prolapse that are 3 used to form my opinions on treatment of prolapse 4 or of this patient. 5 Q. To the extent you directly relied on an 6 article or a piece of literature in your report, 7 the only way for me to know that by reading your 8 report would be to read the report and see the 9 citation, correct? 10 A. If I specifically quoted a figure or a 11 fact out of a report, then I cited it on these 12 pages here. Can you -- do you want to rephrase 13 your question? 14 Q. No. 15 A. Okay. 16 Q. If we go to Attachment A to your report, 17 it's a curriculum vitae. Is that your current 18 curriculum vitae? 19 A. Yes. 20 Q. Within your curriculum vitae is a list 21 of publications. Do any of the publications 22 directly relate to the prolapse -- Prolift? 23 MR. COMBS: Object to form. 24 MR. SLATER: I'll reask the question. 25 BY MR. SLATER:</p>

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<p style="text-align: right;">Page 10</p> <p>1 Q. The list of publications in your</p> <p>2 curriculum vitae, do any of them specifically</p> <p>3 address the Prolift?</p> <p>4 A. No.</p> <p>5 Q. Do any of your publications specifically</p> <p>6 address the TVM technique for the treatment of</p> <p>7 prolapse?</p> <p>8 A. No.</p> <p>9 Q. Would you agree with me that the Prolift</p> <p>10 is an augmentation -- or rephrase.</p> <p>11 Would you agree with me that the Prolift</p> <p>12 is an alternative surgical procedure for the</p> <p>13 treatment of prolapse as compared to other</p> <p>14 techniques that are available to physicians?</p> <p>15 A. Yes.</p> <p>16 Q. You said yes, correct?</p> <p>17 A. Yes.</p> <p>18 Q. Do any of your publications address</p> <p>19 complications from the use of mesh to treat</p> <p>20 prolapse?</p> <p>21 A. There was the abstract from IUGA where</p> <p>22 the lead author was Furlong where we reported on</p> <p>23 some complications after vaginal mesh surgery, not</p> <p>24 specifically the Prolift.</p> <p>25 Q. Is that listed on your list there?</p>	<p style="text-align: right;">Page 12</p> <p>1 A. Correct.</p> <p>2 Q. And this poster was detailing</p> <p>3 complications that had been seen by yourself and</p> <p>4 your co-authors with the use of grafts and mesh</p> <p>5 augmentation in the treatment of prolapse?</p> <p>6 A. Yes.</p> <p>7 Q. Did that include complications seen from</p> <p>8 Prolift?</p> <p>9 A. The abstract does not specify which</p> <p>10 products were used during this time period, but I</p> <p>11 imagine some are Prolift.</p> <p>12 Q. As you sit here now do you know whether</p> <p>13 or not any of these complications related to the</p> <p>14 use of the Prolift?</p> <p>15 A. It was the time period when our practice</p> <p>16 did use Prolift. So, I -- I would say yeah, some</p> <p>17 of them were Prolift. But how many, I can't tell</p> <p>18 you. We just separated by biologic versus</p> <p>19 synthetic.</p> <p>20 Q. And just so I understand some</p> <p>21 vocabulary. This was a poster presentation, the</p> <p>22 Furlong presentation. That's not an abstract.</p> <p>23 That's a poster. There's a difference, correct?</p> <p>24 A. It was a published abstract and it was a</p> <p>25 poster.</p>
<p style="text-align: right;">Page 11</p> <p>1 A. I believe it is. I'll check it.</p> <p>2 Q. Can you tell me where it is. I might</p> <p>3 just be overlooking it.</p> <p>4 A. Page 40.</p> <p>5 Q. Page 40?</p> <p>6 A. On my report.</p> <p>7 Q. Let me look. Let me go back.</p> <p>8 On page 40 of your report, which is your</p> <p>9 list of references, there is an article --</p> <p>10 rephrase.</p> <p>11 On the list of literature at the end of</p> <p>12 your report on page 40 there is a reference to</p> <p>13 Furlong, F-u-r-l-o-n-g, Elser and Moen. What is</p> <p>14 that?</p> <p>15 A. It's an abstract that was a poster at</p> <p>16 the SGS meeting in 2009. We reported on</p> <p>17 complications related to biologic graft or</p> <p>18 synthetic mesh used in vaginal surgery for</p> <p>19 prolapse.</p> <p>20 Q. At the SGS meeting in New Orleans in</p> <p>21 2009 you presented a poster presentation, correct?</p> <p>22 A. It was a poster.</p> <p>23 Q. And that means the poster was presented,</p> <p>24 you did not actually have a speaking or a</p> <p>25 presentation role at that meeting, correct?</p>	<p style="text-align: right;">Page 13</p> <p>1 Q. When you say there was a published</p> <p>2 poster, what was there some sort of a booklet of</p> <p>3 presentations that was circulated in connection</p> <p>4 with that meeting?</p> <p>5 A. Well, the Journal of Pelvic Medicine and</p> <p>6 Surgery has a list of published abstracts that were</p> <p>7 accepted for the meeting.</p> <p>8 Q. So, there was a poster presentation. Is</p> <p>9 the abstract exactly the same as the poster?</p> <p>10 A. I can't say exactly. Sometimes there is</p> <p>11 an additional picture on posters. I don't remember</p> <p>12 specifically for this one. But no additional</p> <p>13 information.</p> <p>14 Q. Is the Furlong, Elser, Moen presentation</p> <p>15 on complications related to graft or mesh</p> <p>16 augmentation listed anywhere in your curriculum</p> <p>17 vitae?</p> <p>18 A. No, I don't see it.</p> <p>19 Q. Why didn't you list this poster</p> <p>20 presentation which you've told me also was an</p> <p>21 abstract, why isn't that listed in your curriculum</p> <p>22 vitae?</p> <p>23 A. Oversight.</p> <p>24 Q. Are there any other abstracts,</p> <p>25 presentations or publications of yours that relate</p>

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<p style="text-align: right;">Page 14</p> <p>1 to the use of mesh to treat prolapse that are not</p> <p>2 listed in your curriculum vitae?</p> <p>3 A. Not that I'm aware of.</p> <p>4 Q. How about with regard to the treatment</p> <p>5 of stress incontinence?</p> <p>6 A. Not that I'm aware of.</p> <p>7 Q. Was there ever a time when this</p> <p>8 presentation was listed in your CV and that it was</p> <p>9 deleted for some reason?</p> <p>10 A. No. I think it's more a matter of</p> <p>11 recordkeeping that I didn't always write down my</p> <p>12 abstracts.</p> <p>13 Q. If I request counsel to get that from</p> <p>14 you, would you be able to provide to me a copy of</p> <p>15 the poster and the abstract?</p> <p>16 MR. COMBS: Yeah, Adam, we'll be glad to.</p> <p>17 It's in the body of her report, the information</p> <p>18 from that. But, yes, we will provide you a copy of</p> <p>19 that abstract.</p> <p>20 MR. SLATER: And the poster as well, okay?</p> <p>21 MR. COMBS: If, if we have a copy of the</p> <p>22 poster we'll provide that to you. I don't</p> <p>23 personally have a copy of the poster, but I can</p> <p>24 tell you that I can get you a copy of the abstract.</p> <p>25 If we have the poster, we'll give you the poster</p>	<p style="text-align: right;">Page 16</p> <p>1 vaginally or for a sacrocolpopexy potentially.</p> <p>2 Q. Why did you stop using Gynemesh PS as</p> <p>3 sold at that product?</p> <p>4 A. For sacrocolpopexy I wanted a longer</p> <p>5 piece of mesh, and for the vaginal mesh procedures</p> <p>6 we transitioned into kits when they became</p> <p>7 available.</p> <p>8 Q. When did you first begin to use a kit</p> <p>9 for the treatment of prolapse?</p> <p>10 A. I don't recall exactly, but it would</p> <p>11 have been around 2005, 2006.</p> <p>12 Q. Which kit did you first use?</p> <p>13 A. Well, I had -- I had actually used the</p> <p>14 Posterior IVS initially before Prolift was</p> <p>15 available.</p> <p>16 Q. Are you saying you first used the</p> <p>17 Posterior IVS and then you went to the Prolift?</p> <p>18 A. Correct.</p> <p>19 Q. Other than the Posterior IVS and the</p> <p>20 Prolift have you used any other kits for the</p> <p>21 treatment of prolapse?</p> <p>22 A. I have. I had used the Apogee/Perigee.</p> <p>23 I've used the Elevate. I have used the Pinnacle.</p> <p>24 Q. I'd like to get the chronology of your</p> <p>25 use of the kits. You started with the</p>
<p style="text-align: right;">Page 15</p> <p>1 too.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. Dr. Elser, do you have a copy of the</p> <p>4 poster that was presented?</p> <p>5 A. I do not have a copy.</p> <p>6 Q. Do you know if Dr. Furlong or Dr. Moen</p> <p>7 has it?</p> <p>8 A. Dr. Moen would not have it and I don't</p> <p>9 know if Dr. Furlong has it.</p> <p>10 Q. I will just ask that an effort be made</p> <p>11 to identify it and produce it.</p> <p>12 Did you utilize Gynemesh PS in your</p> <p>13 medical practice?</p> <p>14 A. Yes.</p> <p>15 Q. During what time period?</p> <p>16 A. It would have been prior to 2005.</p> <p>17 Q. Can you tell me more specific than that</p> <p>18 when you used it, for how long?</p> <p>19 A. No, I don't recall.</p> <p>20 Q. When you used Gynemesh PS prior to 2005,</p> <p>21 did you just use that where you would cut portions</p> <p>22 of it to help you in treating prolapse where you</p> <p>23 were using native tissue repair?</p> <p>24 A. Well, I would use it for a mesh</p> <p>25 augmented repair where we cut our own mesh to place</p>	<p style="text-align: right;">Page 17</p> <p>1 Posterior IVS. When did you use that? During what</p> <p>2 time period?</p> <p>3 A. I don't -- I don't have the years. I</p> <p>4 don't have records available to look at to tell you</p> <p>5 what years I used it.</p> <p>6 Q. Well, you said earlier you believed it</p> <p>7 was about 2005, 2006 when you began to use the</p> <p>8 Posterior IVS?</p> <p>9 A. When I began to use Prolift. So, let me</p> <p>10 clarify that. Posterior IVS, I would have to go</p> <p>11 back and look when it was available, when I had</p> <p>12 used it.</p> <p>13 Q. The first kit that you used for the</p> <p>14 treatment of prolapse was the Posterior IVS,</p> <p>15 correct?</p> <p>16 A. Correct.</p> <p>17 Q. And then sometime around 2005, 2006 you</p> <p>18 began to use the Prolift?</p> <p>19 A. Right.</p> <p>20 Q. At the time you began to use the Prolift</p> <p>21 had you used any other kits besides the</p> <p>22 Posterior IVS?</p> <p>23 A. I don't recall the chronology of whether</p> <p>24 I had used Perigee/Apogee, you know, around the</p> <p>25 same time I started using Prolift.</p>

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<p style="text-align: right;">Page 18</p> <p>1 Q. For how long did you use the</p> <p>2 Apogee/Perigee kits?</p> <p>3 A. Maybe a year.</p> <p>4 Q. How many times would you estimate you</p> <p>5 used those total?</p> <p>6 A. I'm going to have to make estimates here</p> <p>7 because I don't have records and haven't looked at</p> <p>8 this. I would say under a dozen for the</p> <p>9 Perigee/Apogee.</p> <p>10 Q. You began to use the Prolift in 2005 or</p> <p>11 2006. When did you stop using the Prolift?</p> <p>12 A. When it was no longer available.</p> <p>13 Q. And when was it that it ceased to be</p> <p>14 available to you?</p> <p>15 A. Oh, I don't recall the exact date.</p> <p>16 Q. How many times did you use the Prolift</p> <p>17 to treat prolapse?</p> <p>18 A. Again, this is going to be an estimate.</p> <p>19 Over 100.</p> <p>20 Q. During the time that you were using the</p> <p>21 Prolift, did you also continue to do native tissue</p> <p>22 repairs with suture?</p> <p>23 A. Yes.</p> <p>24 Q. Did you view the native tissue repairs</p> <p>25 with suture as an alternative to Prolift and vice</p>	<p style="text-align: right;">Page 20</p> <p>1 and probably others that I don't remember.</p> <p>2 Q. What do you currently use?</p> <p>3 A. Most commonly the Restorelle.</p> <p>4 Q. In terms of your use of the Prolift, did</p> <p>5 there come a time when the frequency of your use of</p> <p>6 the Prolift began to diminish?</p> <p>7 A. Yes.</p> <p>8 Q. When was that?</p> <p>9 A. Most notably, vaginal mesh in general</p> <p>10 would be after the 2011 FDA notification came out</p> <p>11 and patients were very wary of vaginal mesh.</p> <p>12 But before that we were -- my partner</p> <p>13 and I were going to be involved in a Pinnacle study</p> <p>14 and we were using Pinnacle more to prepare for the</p> <p>15 study.</p> <p>16 Q. When did you use the Pinnacle, during</p> <p>17 what time period?</p> <p>18 A. I don't recall the years. It would --</p> <p>19 it was from whenever it became available until</p> <p>20 2011.</p> <p>21 Q. Do you have an estimate of when the</p> <p>22 Pinnacle became available?</p> <p>23 A. I don't recall.</p> <p>24 Q. Would it be around 2007 or 2008?</p> <p>25 A. I would be --</p>
<p style="text-align: right;">Page 19</p> <p>1 versa meaning that in any patient you would look at</p> <p>2 risks/benefits and then consult with the patient</p> <p>3 and determine which procedure would be done for</p> <p>4 that patient if either one was appropriate for that</p> <p>5 condition?</p> <p>6 A. That's right. It would be based on</p> <p>7 patient selection.</p> <p>8 Q. You also have performed abdominal</p> <p>9 sacrocolpopexy, correct?</p> <p>10 A. Yes.</p> <p>11 Q. Have you been performing that procedure</p> <p>12 since at least 2005 up until the present?</p> <p>13 A. Performed my first one before 1995.</p> <p>14 Q. In terms of alternative treatments for a</p> <p>15 patient, abdominal sacrocolpopexy would be one of</p> <p>16 the alternatives if in fact there was a prolapse in</p> <p>17 that part of the pelvis that would be appropriate</p> <p>18 for that treatment?</p> <p>19 A. Right. It's one of the -- one of the</p> <p>20 surgeries we have available to treat prolapse.</p> <p>21 Q. What meshes have you used for abdominal</p> <p>22 sacrocolpopexy?</p> <p>23 A. I have used Gore-Tex graft, which</p> <p>24 can't -- is not really a mesh. I have used Marlex,</p> <p>25 Mersilene, Gynemesh, IntePro and Restorelle, Alyte</p>	<p style="text-align: right;">Page 21</p> <p>1 Q. Does that sound correct?</p> <p>2 A. I would be guessing. That sounds around</p> <p>3 the right time.</p> <p>4 Q. When you began to use the Pinnacle,</p> <p>5 you -- did you stop using the Prolift altogether or</p> <p>6 just significantly decrease your use of the</p> <p>7 Prolift?</p> <p>8 A. Decreased my use.</p> <p>9 Q. And why did you begin to use the</p> <p>10 Pinnacle rather than the Prolift?</p> <p>11 A. I wanted to be familiar with the product</p> <p>12 as we were going to enroll patients in a clinical</p> <p>13 study.</p> <p>14 Q. When that point came were you offering</p> <p>15 the Prolift and the Pinnacle as options to your</p> <p>16 patients or were you telling them that if they want</p> <p>17 to have a kit done, you were offering them the</p> <p>18 Pinnacle at that point?</p> <p>19 A. I would have talked to the patient about</p> <p>20 vaginal mesh repair and then I chose the kit</p> <p>21 typically.</p> <p>22 Q. So, when you consented patients with</p> <p>23 mesh repair kits, you didn't speak to them about</p> <p>24 the specific manufacturer and compared the</p> <p>25 different kits that were available that you were</p>

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<p style="text-align: right;">Page 22</p> <p>1 able to use. You just talked about vaginal mesh in 2 general and then you chose the kit. Is that 3 correct? 4 A. Typically. 5 Q. Were there qualitative differences from 6 your perspective between the Pinnacle and the 7 Prolift that would make one or the other more 8 appropriate for certain patients? 9 A. No. 10 Q. How many Pinnacle procedures would you 11 estimate you did? 12 A. Again, a guess. Around 40. 13 Q. When did you stop using the Pinnacle? 14 A. I don't think I've used it in about 15 three years. 16 Q. Sometime in 2011? 17 A. That sounds right. 18 Q. When did you begin to use the Elevate? 19 A. I think around 2011. 20 Q. Why did you begin to use the Elevate? 21 A. I was interested in the way it was 22 attached and I liked the mesh it had as well and 23 that's the product I'm currently using when I 24 perform vaginally mesh-augmented procedures. 25 Q. Are there any significant differences</p>	<p style="text-align: right;">Page 24</p> <p>1 2011, at that point did you cease using the 2 Prolift? 3 A. It was close to the same time, but it 4 was not exclusive that I necessarily went to one 5 and abandoned the other when both were available. 6 Q. At the point when you began to use the 7 Elevate, were the vast majority of procedures that 8 you did where a mesh kit was involved, was that 9 done with the Elevate at that point going forward? 10 A. Yes. 11 Q. From the point when you began to use the 12 Elevate, how many Prolift procedures did you use -- 13 rephrase that. 14 From the point you began to use the 15 Elevate, how many Prolift procedures did you do on 16 a going-forward basis? 17 A. I don't know that number. 18 Q. It would be less than two or three, 19 wouldn't it? 20 A. I don't know. 21 Q. It would be less than five, right? 22 A. I don't recall a number. It was not a 23 set decision to abandon one product and move to the 24 other. So, I might have used either one depending 25 on what was available in the OR.</p>
<p style="text-align: right;">Page 23</p> <p>1 between the Elevate and the Prolift? 2 A. The Elevate has attachments that are 3 directed from the vaginal incision into the 4 sacrospinous ligament and into the white line and 5 there is not a trocar pass through the obturator 6 membrane from the outside. 7 Q. One significant difference between the 8 Elevate and the Prolift is that the Elevate does 9 not have trocar passes, correct? 10 A. Right. From the outside in. It has 11 trocars that you pass little mesh arms with, but it 12 doesn't have the trocar pass from the outside in 13 through the obturator membrane. 14 Q. The mesh for the Elevate is different 15 from the Prolift mesh, correct? 16 A. They're both polypropylene meshes. 17 There may be some differences. 18 Q. Well, wouldn't it be true that from your 19 perspective there is a difference, for example, in 20 the weight and the flexibility of the Elevate mesh 21 versus the Prolift mesh? 22 A. I have not compared the two side by side 23 in a while or read about the differences recently. 24 So, I would have to look at both of them. 25 Q. When you began to use the Elevate in</p>	<p style="text-align: right;">Page 25</p> <p>1 Q. The fact that there were no external 2 trocar passes with the Elevate, you saw that as a 3 benefit from a safety perspective as compared to 4 the Prolift, correct? 5 MR. COMBS: Object to the form. 6 BY THE WITNESS: 7 A. I saw it as potential benefit, but I -- 8 it did not determine it was a safer product. 9 MR. SLATER: Move to strike from "but" 10 forward. 11 BY MR. SLATER: 12 Q. In your patients in evaluating the 13 risk/benefit profile, is it true that you saw the 14 Elevate with no external trocar passes as offering 15 a safety advantage compared to the Prolift which 16 had the external trocar passes? 17 A. Yes, if I can explain. The -- the 18 trocar pass, the risk was a potential for injury to 19 the bladder during the procedure or a risk of 20 injury to a blood vessel during the passage. 21 In my experience I experienced one 22 bladder injury using a Prolift and never had a 23 hemorrhage or hitting a blood vessel, so it was not 24 a major reason to make a switch necessarily. It 25 was a potential decreasing risk of a very rare</p>

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<p style="text-align: right;">Page 26</p> <p>1 complication.</p> <p>2 MR. SLATER: Move to strike after "yes."</p> <p>3 BY MR. SLATER:</p> <p>4 Q. One of the risks with the external</p> <p>5 trocar passes with the Prolift is that nerves will</p> <p>6 be damaged, correct?</p> <p>7 A. Any time you have a surgery there is a</p> <p>8 risk that nerve will be damaged.</p> <p>9 Q. With the external trocar passes with the</p> <p>10 Prolift, one of the risks is that the trocar will</p> <p>11 enter the body and damage nerves, correct?</p> <p>12 A. Can you be more specific? Are you</p> <p>13 asking about a specific nerve or any kind of nerve?</p> <p>14 Q. I'm right now asking about nerves in</p> <p>15 general. That's one of the risks, right?</p> <p>16 A. That's a risk of any surgery.</p> <p>17 MR. SLATER: Move to strike.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. I know that -- I was told at the start</p> <p>20 of the deposition, Dr. Elser, that there is a hard</p> <p>21 stop time. I've been given a limited time to take</p> <p>22 the deposition. So I'd appreciate if I ask you a</p> <p>23 direct question, if we just stick with that</p> <p>24 question, that way we can move more efficiently.</p> <p>25 MR. COMBS: Okay. And if we're going to be</p>	<p style="text-align: right;">Page 28</p> <p>1 Q. Dr. Elser, with the external trocar</p> <p>2 passes from the Prolift, one of the risks is that</p> <p>3 the trocar can injure a nerve during the procedure,</p> <p>4 correct?</p> <p>5 A. Yes. There is a risk a trocar can</p> <p>6 injure a nerve and there's a risk a scalpel can</p> <p>7 injure a nerve. There is a risk a scissor can</p> <p>8 injure a nerve.</p> <p>9 MR. SLATER: Move to strike from "and"</p> <p>10 forward.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. Did you ever tell anybody that you</p> <p>13 thought the Elevate had certain safety advantages</p> <p>14 with regard -- as compared to the Prolift?</p> <p>15 MR. COMBS: Object to form.</p> <p>16 BY THE WITNESS:</p> <p>17 A. I don't recall that.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. You wouldn't deny it if somebody were to</p> <p>20 say that, you wouldn't be surprised if you said</p> <p>21 that, would you?</p> <p>22 A. I would be surprised.</p> <p>23 Q. Let's go back to your CV -- I mean your</p> <p>24 report. Rephrase.</p> <p>25 Let's go to Attachment B to your report.</p>
<p style="text-align: right;">Page 27</p> <p>1 putting statements on the record, obviously we sat</p> <p>2 here for more than 45 minutes waiting on you to be</p> <p>3 ready to start the deposition. We are ready to go</p> <p>4 forward. Let's just go forward.</p> <p>5 MR. SLATER: Mr. Combs, I was a half hour late</p> <p>6 because on the Interstate 287 south, which I drive</p> <p>7 to my office each day, there was a fatal accident.</p> <p>8 So, I was diverted around it and saw a body</p> <p>9 underneath a white sheet with emergency vehicles</p> <p>10 around it, which caused me to be 30 minutes late.</p> <p>11 So, I apologize for that, but that was something</p> <p>12 beyond my control.</p> <p>13 MR. COMBS: Well, let's not act like that the</p> <p>14 reason that if the deposition isn't concluded by</p> <p>15 5:00 is going to be because Dr. Elser isn't</p> <p>16 answering your questions. She is answering your</p> <p>17 questions.</p> <p>18 MR. SLATER: I'm sorry. I'm not acting like</p> <p>19 anything. The last question was not responsive. I</p> <p>20 move to strike. Witnesses who are expert should</p> <p>21 answer directly. That's my understanding.</p> <p>22 MR. COMBS: Well, she is answering your</p> <p>23 questions.</p> <p>24 MR. SLATER: Okay. Thank you very much.</p> <p>25 BY MR. SLATER:</p>	<p style="text-align: right;">Page 29</p> <p>1 This is a list, "Reliance List in Addition to</p> <p>2 Materials Referenced in Report." That's what it's</p> <p>3 titled, correct?</p> <p>4 A. Correct.</p> <p>5 Q. The first portion of this list is a list</p> <p>6 of articles and literature, correct?</p> <p>7 A. Correct.</p> <p>8 Q. Did you compile this list or was this</p> <p>9 compiled for you?</p> <p>10 A. This was compiled for me.</p> <p>11 Q. This list was compiled for you by</p> <p>12 counsel, correct?</p> <p>13 A. Yes.</p> <p>14 Q. Is that correct?</p> <p>15 A. Yes.</p> <p>16 Q. Throughout your report and your</p> <p>17 literature list and the list of literature listed</p> <p>18 are articles relating to midurethral slings and the</p> <p>19 TVT products, correct?</p> <p>20 A. Correct.</p> <p>21 Q. In forming your opinions, did you rely</p> <p>22 on midurethral slings and the TVT to form any of</p> <p>23 your opinions regarding safety and efficacy of the</p> <p>24 Prolift?</p> <p>25 A. I primarily referred -- I relied on</p>

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<p style="text-align: right;">Page 30</p> <p>1 articles specifically related to prolapse and my 2 experience in treating prolapse. But slings did 3 give us experience with vaginal mesh. 4 Q. Here's what I want to know: In forming 5 your opinions in this case, are you relying on 6 literature or studies with regard to the treatment 7 of stress urinary incontinence with midurethral 8 slings like the TVT products? 9 MR. COMBS: Asked and answered. 10 BY THE WITNESS: 11 A. Are you -- can I ask a clarification? 12 BY MR. SLATER: 13 Q. Yes. 14 A. Are you asking if I'm going to pull data 15 from a sling article and say it relates to problems 16 with prolapse repair? 17 Q. Let's start with this. Are you relying 18 on any data or findings in any of the TVT or 19 midurethral sling literature in order to form your 20 opinions in this case regarding the Prolift? 21 A. I don't think I am specifically. 22 Q. Nothing you can point to now, correct? 23 A. Can you say that again. I didn't hear 24 it. 25 Q. Nothing that you could point to now,</p>	<p style="text-align: right;">Page 32</p> <p>1 MR. COMBS: Yes, we'll figure out some way to 2 send that to you. 3 MR. SLATER: Okay. 4 BY MR. SLATER: 5 Q. What's the other article? 6 A. That's the only one I specifically have 7 in mind right now. 8 Q. Who is the author? 9 A. If you give -- if you want to wait until 10 the break when I un-mike myself, I'll pull it out 11 of my bag. 12 Q. Sure. We'll just talk about it later. 13 MR. COMBS: Adam, just bear with me for just 14 one second. 15 MR. SLATER: I don't want to hold things up. 16 I am not that eager. We can cover it after a 17 break. 18 MR. COMBS: That's fine. I was just telling 19 Paul to remind me that at the break, we'll get that 20 pdf to you. 21 MR. SLATER: Thanks. 22 MR. COMBS: Okay. 23 MR. SLATER: I'm psyched. 24 MR. COMBS: Good. 25 BY MR. SLATER:</p>
<p style="text-align: right;">Page 31</p> <p>1 right? 2 A. Correct. 3 Q. Did you -- well, rephrase that. Let me 4 withdraw that. 5 If there was an article that you thought 6 was important to you in forming your opinions, 7 would it be fair to say it would be in the 8 literature list at the end of your report that 9 starts on page 39? 10 MR. COMBS: Object to form. 11 BY THE WITNESS: 12 A. I believe I have one or two more 13 articles that I brought with me that I may want to 14 point to today that I've pulled after this list was 15 made. 16 BY MR. SLATER: 17 Q. Which articles are those? 18 A. One specifically is an article on 19 myofascial pain. 20 Q. Is it listed anywhere in your report or 21 your list of reliance materials? 22 A. No. 23 MR. SLATER: Well, I don't have that. So is 24 there any way for that article to be sent to me, 25 Phil?</p>	<p style="text-align: right;">Page 33</p> <p>1 Q. Okay. I am looking still at your 2 reliance list. 3 After the list of literature there's a 4 list that is a list of what's called "Production 5 Materials," and that list goes I want to say to the 6 end, almost to the end. Let me rephrase it. 7 In your list of -- your reliance list, 8 after the medical literature list, there is a list 9 of what's called "Production Materials." What is 10 that list? 11 A. It looks like a list of some memos from 12 Gynecare Ethicon, some publications such as slide 13 decks and monographs and includes anatomy videos. 14 Q. If we continue through it, it includes 15 Clinical Expert Reports, e-mails, IFUs, TVT 16 documents, TVT-O documents, various patient 17 brochures, various slide decks and videos. 18 Correct? 19 A. Correct. 20 Q. Did you read all these documents and 21 watch all these videos? 22 A. I did not. 23 Q. Was this a list that was compiled and 24 given to you by counsel? 25 A. Yes.</p>

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<p style="text-align: right;">Page 34</p> <p>1 Q. Are you relying specifically on any of</p> <p>2 these documents for your opinions?</p> <p>3 A. I'll be looking to the IFU and the</p> <p>4 resource monograph as well as --</p> <p>5 Q. Anything else?</p> <p>6 A. As well as a video on Prolift.</p> <p>7 Q. Which video on Prolift?</p> <p>8 A. I don't know how to locate it here on</p> <p>9 this list. It's a 2005 video narrated --</p> <p>10 Q. What happens in that video?</p> <p>11 A. Pardon?</p> <p>12 Q. What happens in that video?</p> <p>13 A. It has an animation of pelvic anatomy</p> <p>14 and then of mesh placement.</p> <p>15 Q. And it's an animated video, correct?</p> <p>16 A. Correct.</p> <p>17 Q. Is that one where the narrator talks</p> <p>18 about what's happening and you see the mesh arms</p> <p>19 coming through the exit points and all that sort of</p> <p>20 thing?</p> <p>21 A. Yeah, it's a great description.</p> <p>22 Q. Anything else on this list of production</p> <p>23 materials you're relying on for your opinions?</p> <p>24 A. No, those are the ones that come to</p> <p>25 mind.</p>	<p style="text-align: right;">Page 36</p> <p>1 Q. What was your answer?</p> <p>2 A. No.</p> <p>3 Q. Did you assume that when you read an IFU</p> <p>4 from a company regarding a mesh kit that the</p> <p>5 company was disclosing to you those complications</p> <p>6 and risks that could be significant for the patient</p> <p>7 that were known to the company?</p> <p>8 A. No. I always thought of the IFU as</p> <p>9 helping to delineate steps of the procedure that</p> <p>10 might be unique to this procedure and to warn of</p> <p>11 any complications that might not be known to the</p> <p>12 average surgeon. But it was not something I relied</p> <p>13 on to know all the complications related to a</p> <p>14 surgery.</p> <p>15 Q. Did you assume that when you read an IFU</p> <p>16 for a medical device that the company was</p> <p>17 disclosing any risks and complications that would</p> <p>18 be inherent to the mesh material so that you would</p> <p>19 know what those risks were?</p> <p>20 A. No. If we were already using the mesh,</p> <p>21 I would assume I would look to the IFU to tell me</p> <p>22 what was specific about this delivery system.</p> <p>23 Q. Do you know whether or not one of the</p> <p>24 purposes of the IFU was to disclose each of the</p> <p>25 risks and complications that can occur with the use</p>
<p style="text-align: right;">Page 35</p> <p>1 Q. Did you read any depositions of any</p> <p>2 Ethicon employees?</p> <p>3 A. No.</p> <p>4 Q. Do you know what standards Ethicon</p> <p>5 applied in terms of what needed to be included in</p> <p>6 warnings about the Prolift?</p> <p>7 A. No, I don't.</p> <p>8 Q. Have you in your career ever been</p> <p>9 involved in writing or preparing warnings for a</p> <p>10 medical device?</p> <p>11 A. For a company?</p> <p>12 Q. Yes.</p> <p>13 A. No.</p> <p>14 Q. In your practice did you read IFUs</p> <p>15 for -- rephrase.</p> <p>16 In your practice did you read the IFU</p> <p>17 for each mesh kit before using it?</p> <p>18 A. Yes. That was typically my practice.</p> <p>19 Q. Did you assume that the IFU was</p> <p>20 disclosing to you each of the risks and</p> <p>21 complications the company knew could occur with the</p> <p>22 kit that you were considering using?</p> <p>23 A. No.</p> <p>24 MR. COMBS: Object to the form.</p> <p>25 BY MR. SLATER:</p>	<p style="text-align: right;">Page 37</p> <p>1 of that mesh kit in a woman's body?</p> <p>2 A. I've never thought an IFU would tell me</p> <p>3 every risk.</p> <p>4 Q. Well, as you sit here now do you have an</p> <p>5 understanding of any standard whatsoever from any</p> <p>6 source as to what risks and complications are</p> <p>7 supposed to be disclosed in an IFU?</p> <p>8 A. No.</p> <p>9 MR. COMBS: Object to the form.</p> <p>10 BY MR. SLATER:</p> <p>11 Q. When you're giving your opinions as to</p> <p>12 whether or not the IFU adequately warns of risks</p> <p>13 and complications, you're just basing that on your</p> <p>14 own opinions based on your own experience and what</p> <p>15 you think is reasonable. Is that fair?</p> <p>16 A. That's fair.</p> <p>17 Q. You're not relying on any objective</p> <p>18 standard from any source, correct?</p> <p>19 A. Correct.</p> <p>20 Q. And you're not corroborating your --</p> <p>21 rephrase.</p> <p>22 Have you made any effort to corroborate</p> <p>23 your own opinion as to what needs to be in a</p> <p>24 warning in an IFU by looking to what Ethicon's</p> <p>25 professionals believed needed to be in there just</p>

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<p style="text-align: right;">Page 38</p> <p>1 so you could see whether the standard you were</p> <p>2 applying was consistent with what someone in the</p> <p>3 medical device industry would apply? Did you ever</p> <p>4 do that?</p> <p>5 A. No.</p> <p>6 MR. COMBS: Object to form.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. Are you aware of whether there are FDA</p> <p>9 regulations which provide for what type of</p> <p>10 information is supposed to be provided in an IFU?</p> <p>11 A. No.</p> <p>12 Q. Have you looked at any internal</p> <p>13 documents at all, whether it's an e-mail, whether</p> <p>14 it's a deposition, anything, from Ethicon or any</p> <p>15 testimony from anyone in Ethicon, regarding what</p> <p>16 FDA regulations would require to be disclosed in an</p> <p>17 IFU?</p> <p>18 A. No.</p> <p>19 Q. Have you made any effort before today to</p> <p>20 find out what FDA regulations require a medical</p> <p>21 device company to disclose in an IFU?</p> <p>22 A. No.</p> <p>23 Q. Earlier you told me what you expected to</p> <p>24 see in an IFU. That's -- is it fair to say that's</p> <p>25 the standard you applied as to what you think needs</p>	<p style="text-align: right;">Page 40</p> <p>1 Q. And your background and experience is</p> <p>2 not necessarily the same as that for other</p> <p>3 physicians who would consider or considered using</p> <p>4 the Prolift, correct?</p> <p>5 A. Correct.</p> <p>6 Q. And, in fact, it may be that you might</p> <p>7 know about a particular potential complication from</p> <p>8 your experience and another doctor considering</p> <p>9 using the Prolift might not know about that</p> <p>10 potential complication, correct?</p> <p>11 A. Well, correct, but from my experience</p> <p>12 and from the literature and attending conferences.</p> <p>13 So, I'm not relying solely on my experience in my</p> <p>14 little practice.</p> <p>15 Q. Well, this is my question.</p> <p>16 MR. SLATER: Well, first of all, move to</p> <p>17 strike after "correct."</p> <p>18 BY MR. SLATER:</p> <p>19 Q. Your standard for what needs to be</p> <p>20 disclosed in the Prolift IFU is not an objective</p> <p>21 standard where you would say this is the standard</p> <p>22 across the board that is applied. It's the</p> <p>23 standard that Dr. Elser has for what needs to be in</p> <p>24 an IFU. Correct?</p> <p>25 MR. COMBS: Object to the form.</p>
<p style="text-align: right;">Page 39</p> <p>1 to be disclosed in an IFU?</p> <p>2 MR. COMBS: Object to form.</p> <p>3 BY THE WITNESS:</p> <p>4 A. Yes.</p> <p>5 BY MR. SLATER:</p> <p>6 Q. In terms of whether or not Ethicon</p> <p>7 adequately warned, if it turns out that Ethicon had</p> <p>8 information, which if you applied Ethicon's own</p> <p>9 warning standards, the standards that their medical</p> <p>10 people said they were applying and the Regulatory</p> <p>11 Affairs people said they were applying, and if</p> <p>12 Ethicon failed to provide that information, would</p> <p>13 you agree that would be a failure to provide an</p> <p>14 adequate warning?</p> <p>15 MR. COMBS: Object to form.</p> <p>16 BY THE WITNESS:</p> <p>17 A. No, because I have no idea what their</p> <p>18 Regulatory Affairs department would think was</p> <p>19 adequate and whether that was clinically relevant</p> <p>20 to what I'm doing in surgery.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. Your background and experience is not</p> <p>23 necessarily the same as other doctors who use</p> <p>24 medical devices, correct?</p> <p>25 A. Correct.</p>	<p style="text-align: right;">Page 41</p> <p>1 BY THE WITNESS:</p> <p>2 A. No, I'd like to think that my standards</p> <p>3 would be fairly applicable to a pelvic floor</p> <p>4 reconstructive surgeon.</p> <p>5 BY MR. SLATER:</p> <p>6 Q. What have you ever done to confirm that</p> <p>7 your standard for what needs to be in an IFU --</p> <p>8 well, rephrase.</p> <p>9 Have you ever studied the question of</p> <p>10 what information needs to be in an IFU? Have you</p> <p>11 ever engaged in any study of that question?</p> <p>12 A. No, I have not.</p> <p>13 Q. Have you ever made any effort to confirm</p> <p>14 that your understanding for what needs to be in an</p> <p>15 IFU is consistent with what other doctors believe</p> <p>16 should be in an IFU? Have you ever studied that</p> <p>17 question?</p> <p>18 A. No, I have not.</p> <p>19 Q. As you sit here now you don't know</p> <p>20 whether or not the standard you're applying for</p> <p>21 what needs to be in an IFU is consistent with what</p> <p>22 other doctors think. You don't know that because</p> <p>23 you've never tried to verify that, correct?</p> <p>24 MR. COMBS: Object to form.</p> <p>25 BY THE WITNESS:</p>

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<p style="text-align: right;">Page 42</p> <p>1 A. No, but not studying something formally</p> <p>2 does not mean I haven't discussed IFUs with other</p> <p>3 similar physicians who have similar practices and</p> <p>4 take care of patients who need prolapse repairs.</p> <p>5 MR. SLATER: Move to strike after the word</p> <p>6 "no."</p> <p>7 BY MR. SLATER:</p> <p>8 Q. In doing your work in this case were you</p> <p>9 curious as to what the Regulatory Affairs</p> <p>10 department in Ethicon who are the professionals who</p> <p>11 are required to make sure that an IFU complies with</p> <p>12 FDA regulations, were you curious what they thought</p> <p>13 needed to be in an IFU?</p> <p>14 MR. COMBS: Object to form.</p> <p>15 BY THE WITNESS:</p> <p>16 A. No, I was not.</p> <p>17 BY MR. SLATER:</p> <p>18 Q. You have not reviewed any Ethicon</p> <p>19 internal documents other than those few that you</p> <p>20 listed for me, correct?</p> <p>21 A. Not that I recall right now related to</p> <p>22 this case.</p> <p>23 Q. Is it fair to say you have no idea what</p> <p>24 complications and risks were known to Ethicon</p> <p>25 Medical Affairs and when they were known?</p>	<p style="text-align: right;">Page 44</p> <p>1 A. Correct.</p> <p>2 Q. Would you agree that the scope of</p> <p>3 complications and the consequences of those</p> <p>4 complications which the doctors talk about as</p> <p>5 life-altering and other very severe language, those</p> <p>6 profiles apply to the Prolift, meaning some women</p> <p>7 suffer complications that severe from that device?</p> <p>8 A. I don't recall that language from the</p> <p>9 article specifically. So, I would like to look at</p> <p>10 the article before answering you.</p> <p>11 Q. Do you recall that in the Blandon</p> <p>12 article they talk about complications including</p> <p>13 complex mesh erosions, pain syndromes, dyspareunia,</p> <p>14 the need for multiple surgical interventions to</p> <p>15 treat complications, life-changing symptoms,</p> <p>16 complex mesh erosions at multiple sites, most</p> <p>17 patients with erosions require surgery, multiple</p> <p>18 attempts to excise mesh may be required,</p> <p>19 life-changing complications, incapacitating pelvic</p> <p>20 pain, dyspareunia and large-scale erosions that are</p> <p>21 exceedingly complex and not easily resolved, do you</p> <p>22 recall language to that effect in that article?</p> <p>23 MR. COMBS: Object to form.</p> <p>24 BY THE WITNESS:</p> <p>25 A. I don't know what you're reading from.</p>
<p style="text-align: right;">Page 43</p> <p>1 A. That would be fair.</p> <p>2 Q. Would you agree with me that if Ethicon</p> <p>3 Medical Affairs knew there was a potential risk or</p> <p>4 complication attributable to the Prolift mesh</p> <p>5 implant itself which if it occurred could cause</p> <p>6 severe permanent injury to a woman, that that risk</p> <p>7 should be disclosed in the IFU? Would you agree</p> <p>8 with that statement?</p> <p>9 MR. COMBS: Object to form.</p> <p>10 BY THE WITNESS:</p> <p>11 A. No, I don't think it necessarily needs</p> <p>12 to be in the IFU.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. Have you ever studied the question of</p> <p>15 what risks and complications were known to doctors</p> <p>16 across the country with various backgrounds and</p> <p>17 levels of experience with regard to the use of the</p> <p>18 Prolift? Did you ever study that question?</p> <p>19 A. No.</p> <p>20 Q. And you don't know the answer to that</p> <p>21 question, correct?</p> <p>22 A. Correct.</p> <p>23 Q. One of the references in your article is</p> <p>24 the Blandon article from some doctors at the Mayo</p> <p>25 Clinic, correct?</p>	<p style="text-align: right;">Page 45</p> <p>1 So, I would like to have the article in front of me</p> <p>2 before I can answer you.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. Let me ask you this question. Do you</p> <p>5 agree with me that one of the risks with the</p> <p>6 Prolift is complex mesh erosions?</p> <p>7 A. Can you define "complex mesh erosion"?</p> <p>8 Q. Have you never heard that term used</p> <p>9 before?</p> <p>10 A. It's -- it's not a standard term. So, I</p> <p>11 don't know what you mean by that.</p> <p>12 Q. Are you not familiar with seeing the</p> <p>13 term "complex mesh erosions" in the medical</p> <p>14 literature?</p> <p>15 A. It's -- again, it's not a standard form,</p> <p>16 so everyone may have a different definition of</p> <p>17 that. How are you using it?</p> <p>18 MR. SLATER: Move to strike.</p> <p>19 BY MR. SLATER:</p> <p>20 Q. My question is this: Do you not recall</p> <p>21 seeing the term "complex mesh erosions" in the</p> <p>22 medical literature?</p> <p>23 A. I may have. But in my practice I don't</p> <p>24 describe things that way so I don't know what you</p> <p>25 mean by it.</p>

12 (Pages 42 to 45)

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<p style="text-align: right;">Page 46</p> <p>1 Q. I'll define a complex mesh erosion as</p> <p>2 one that is complex to treat. Do you agree that</p> <p>3 that is a risk with the Prolift?</p> <p>4 MR. COMBS: Object to form.</p> <p>5 BY THE WITNESS:</p> <p>6 A. Okay. We would have to debate what</p> <p>7 "complex to treat" means, but any mesh can be</p> <p>8 complex to treat as can pain after native tissue</p> <p>9 repair.</p> <p>10 MR. SLATER: Move to strike.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. Doctor, I didn't ask you about native</p> <p>13 tissue repair. So I would appreciate if you</p> <p>14 wouldn't talk about it when I don't ask about it</p> <p>15 because it's not helpful for us finishing on time,</p> <p>16 please.</p> <p>17 Do you agree with me that if I define</p> <p>18 "complex mesh erosion" as one that is complex to</p> <p>19 treat, meaning it's not a routine, easy procedure,</p> <p>20 do you agree that is one of the risks with the</p> <p>21 Prolift?</p> <p>22 MR. COMBS: Object to form.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Yes, I agree that pelvic mesh can be</p> <p>25 complex to treat.</p>	<p style="text-align: right;">Page 48</p> <p>1 MR. COMBS: Object to form.</p> <p>2 BY THE WITNESS:</p> <p>3 A. Yes, there can be erosion at more than</p> <p>4 one site after mesh is placed.</p> <p>5 BY MR. SLATER:</p> <p>6 Q. Would you agree with the Prolift that</p> <p>7 the literature shows that most patients with</p> <p>8 erosions require surgery?</p> <p>9 A. In that article.</p> <p>10 Q. Would you agree that with the Prolift</p> <p>11 most women who have erosions, the majority end up</p> <p>12 needing surgery?</p> <p>13 A. No.</p> <p>14 MR. COMBS: Object to form.</p> <p>15 BY MR. SLATER:</p> <p>16 Q. You said no?</p> <p>17 A. I said no. That was the experience of</p> <p>18 these patients in this Mayo Clinic experience, but</p> <p>19 that is not reflected in the other literature or</p> <p>20 necessarily in clinical experience.</p> <p>21 Q. With the Prolift would you agree that</p> <p>22 multiple attempts to excise mesh may be required,</p> <p>23 that's one of the risks?</p> <p>24 A. Yes.</p> <p>25 Q. Would you agree that one of the risks</p>
<p style="text-align: right;">Page 47</p> <p>1 BY MR. SLATER:</p> <p>2 Q. Do you agree that one of the risks with</p> <p>3 the Prolift is that the Prolift can lead to a</p> <p>4 chronic pain syndrome?</p> <p>5 A. Yes.</p> <p>6 Q. Do you agree that one of the risks with</p> <p>7 the Prolift is that the Prolift can cause</p> <p>8 dyspareunia?</p> <p>9 A. Yes. Again, not specific to Prolift,</p> <p>10 but any mesh and any vaginal surgery, although you</p> <p>11 don't want me to mention any vaginal surgery.</p> <p>12 MR. SLATER: Move to strike after the word</p> <p>13 "yes."</p> <p>14 BY MR. SLATER:</p> <p>15 Q. Do you agree with the Prolift that one</p> <p>16 of the risks is the need for multiple surgical</p> <p>17 interventions to treat the complications?</p> <p>18 A. Yes.</p> <p>19 Q. Do you agree that one of the risks with</p> <p>20 the Prolift is that the woman can sustain</p> <p>21 life-changing symptoms?</p> <p>22 A. Yes.</p> <p>23 Q. Do you agree that with the Prolift one</p> <p>24 of the risks is complex mesh erosions at multiple</p> <p>25 sites?</p>	<p style="text-align: right;">Page 49</p> <p>1 with the Prolift is life-changing complications?</p> <p>2 A. I think you already asked about</p> <p>3 life-changing changes, right? Is this a different</p> <p>4 question?</p> <p>5 Q. It is. I asked you about life-changing</p> <p>6 symptoms before. Now I'm asking you a new</p> <p>7 question.</p> <p>8 My question is this: Do you agree with</p> <p>9 the Prolift one of the risks is life-changing</p> <p>10 complications?</p> <p>11 A. Okay. I'm having trouble understanding</p> <p>12 how that's a different question.</p> <p>13 Q. Do you agree that life-changing</p> <p>14 complications is one of the risks with the Prolift?</p> <p>15 Do you agree to that statement?</p> <p>16 A. Yes.</p> <p>17 Q. Do you agree that one of the risks with</p> <p>18 the Prolift is incapacitating pelvic pain?</p> <p>19 A. Yes, patients can have severe pain after</p> <p>20 pelvic mesh is placed and after pelvic surgery.</p> <p>21 MR. SLATER: Move to strike after the word</p> <p>22 "yes."</p> <p>23 BY MR. SLATER:</p> <p>24 Q. Do you agree that one of the risks with</p> <p>25 the Prolift is large-scale erosions that are</p>

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<p style="text-align: right;">Page 50</p> <p>1 exceedingly complex and not easy to resolve?</p> <p>2 MR. COMBS: Object to form.</p> <p>3 BY THE WITNESS:</p> <p>4 A. By "large-scale" do you mean a large</p> <p>5 area in one patient or a large scale meaning lots</p> <p>6 of people in the population?</p> <p>7 BY MR. SLATER:</p> <p>8 Q. Large area in the patient.</p> <p>9 A. Mesh can have a large area of erosion.</p> <p>10 Q. The list of complications and risks I</p> <p>11 just asked you about, do you know whether Ethicon</p> <p>12 knew about those risks on the day the Prolift first</p> <p>13 went to the market?</p> <p>14 A. I don't know.</p> <p>15 Q. If Ethicon knew about that scope of</p> <p>16 risks that I just went through with you on the day</p> <p>17 the Prolift went to the market, do you agree those</p> <p>18 risks should have been disclosed in the IFU?</p> <p>19 MR. COMBS: Object to form.</p> <p>20 BY THE WITNESS:</p> <p>21 A. No. The pelvic surgeons were already</p> <p>22 familiar with placing vaginal mesh.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. When the Prolift came out on the market,</p> <p>25 surgeons were not experienced on any long-term</p>	<p style="text-align: right;">Page 52</p> <p>1 other or no opinion on that question?</p> <p>2 A. No opinion.</p> <p>3 Q. Do you know whether or not the amount of</p> <p>4 mesh placed in the woman's pelvis for treatment of</p> <p>5 prolapse has an impact on the intensity and</p> <p>6 duration of the foreign body reaction and</p> <p>7 inflammatory response?</p> <p>8 A. No.</p> <p>9 Q. Do you have any opinion on that</p> <p>10 question?</p> <p>11 A. No, I don't.</p> <p>12 Q. Am I accurate you do not hold yourself</p> <p>13 out as an expert with regard to the design of</p> <p>14 medical device kits for the treatment of prolapse?</p> <p>15 A. That would be correct.</p> <p>16 Q. And am I correct that I would not expect</p> <p>17 you to offer opinions as to the design of the</p> <p>18 Prolift?</p> <p>19 MR. COMBS: Object to form.</p> <p>20 BY THE WITNESS:</p> <p>21 A. I may offer opinions.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. Am I correct that you do not hold</p> <p>24 yourself out as having expertise or specialized</p> <p>25 knowledge regarding the type of mesh used in the</p>
<p style="text-align: right;">Page 51</p> <p>1 basis with the use of mesh kits like the Prolift</p> <p>2 with that much mesh going into those parts of the</p> <p>3 body, this was something new at that point,</p> <p>4 correct?</p> <p>5 A. The obturator-based placement with the</p> <p>6 mesh arms was new. It doesn't mean that large</p> <p>7 pieces of mesh were not used for prolapse repair</p> <p>8 before this.</p> <p>9 MR. SLATER: Move to strike after the word</p> <p>10 "it."</p> <p>11 BY MR. SLATER:</p> <p>12 Q. Do you know the area of mesh used in the</p> <p>13 Prolift, in any of the Prolift kits?</p> <p>14 A. Not offhand.</p> <p>15 Q. Would you agree with me that as compared</p> <p>16 to the way that mesh was used before the Prolift</p> <p>17 came along that the Prolift provided for more mesh</p> <p>18 to be put in a woman's pelvis than what had been</p> <p>19 previously used?</p> <p>20 A. Yes, for the most part.</p> <p>21 Q. Do you have any information as to</p> <p>22 whether the amount of mesh with the Prolift</p> <p>23 increases the risk of harm to the woman?</p> <p>24 A. No.</p> <p>25 Q. Do you have an opinion one way or the</p>	<p style="text-align: right;">Page 53</p> <p>1 Prolift?</p> <p>2 A. Outside of the Amid classifications, no.</p> <p>3 Q. Do you have any expertise or specialized</p> <p>4 knowledge regarding whether or not a 1 millimeter</p> <p>5 pore size when the mesh is in use in the body has</p> <p>6 any advantages or disadvantages for the patient?</p> <p>7 MR. COMBS: Object to form.</p> <p>8 BY THE WITNESS:</p> <p>9 A. As opposed to other sizes in general or</p> <p>10 bigger or smaller? Do you want to be more</p> <p>11 specific?</p> <p>12 BY MR. SLATER:</p> <p>13 Q. Do you have any -- any specialized</p> <p>14 knowledge or expertise regarding whether or not a</p> <p>15 1 millimeter pore size for the Prolift in actual</p> <p>16 use has any significance for safety for the woman?</p> <p>17 A. Well, in general we want pore size of</p> <p>18 the type 1, which is greater than 75 microns, to</p> <p>19 allow for adequate tissue ingrowth and allowing</p> <p>20 white blood cells in the area.</p> <p>21 MR. SLATER: Move to strike.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. Here's my question. Are any -- do you</p> <p>24 have any opinion -- I'm sorry. Don't -- let's not</p> <p>25 do that.</p>

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<p style="text-align: right;">Page 54</p> <p>1 MR. COMBS: And what's your reference? Let's</p> <p>2 not do what? What are you talking about?</p> <p>3 MR. SLATER: You know, I'm not going to say</p> <p>4 anything for the record. Let's just be careful how</p> <p>5 we proceed.</p> <p>6 MR. COMBS: I have no idea what you're talking</p> <p>7 about. If there is something you want to raise,</p> <p>8 feel free to raise it. If not, let's just move</p> <p>9 forward.</p> <p>10 MR. SLATER: All right. Well, if you're going</p> <p>11 to challenge me, Dr. Elser is continually looking</p> <p>12 at you.</p> <p>13 MR. COMBS: Looking at me?</p> <p>14 MR. SLATER: I think so.</p> <p>15 MR. COMBS: Okay. Well, I wasn't aware of</p> <p>16 that.</p> <p>17 THE WITNESS: I'm trying to look at --</p> <p>18 MR. SLATER: You are wasting time with the</p> <p>19 questioning. I wasn't looking to get into it.</p> <p>20 MR. COMBS: Let's just move on.</p> <p>21 MR. SLATER: Don't laugh. I'm sorry if I am</p> <p>22 amusing you.</p> <p>23 MR. COMBS: Who are you talking to?</p> <p>24 MR. SLATER: You.</p> <p>25 MR. COMBS: What --</p>	<p style="text-align: right;">Page 56</p> <p>1 mesh pore size in a Prolift of either greater or</p> <p>2 less than 1 millimeter when the mesh is under</p> <p>3 strain in use has any significance with regard to</p> <p>4 safety or effectiveness? Am I accurate, you do not</p> <p>5 hold yourself out as having any expertise with</p> <p>6 regard to that question?</p> <p>7 MR. COMBS: Object to the form, asked and</p> <p>8 answered.</p> <p>9 BY THE WITNESS:</p> <p>10 A. Well, I think your word "any" is a</p> <p>11 little troublesome for me there. So...</p> <p>12 BY MR. SLATER:</p> <p>13 Q. Let me ask you the question this way.</p> <p>14 What, if any, significance is there to whether or</p> <p>15 not the pore size of the Prolift is 1 millimeter</p> <p>16 when the mesh is actually in use in the body? Do</p> <p>17 you have any knowledge of that?</p> <p>18 MR. COMBS: Object to the form, asked and</p> <p>19 answered.</p> <p>20 MR. SLATER: It has not been asked and</p> <p>21 answered. That's not fair.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. Please answer the question.</p> <p>24 A. I may have opinion on that.</p> <p>25 Q. What is it?</p>
<p style="text-align: right;">Page 55</p> <p>1 BY MR. SLATER:</p> <p>2 Q. Dr. Elser. My next question is this:</p> <p>3 Am I correct that you do not hold yourself out as</p> <p>4 an expert with regard to whether or not a</p> <p>5 1 millimeter pore size in the Prolift when the mesh</p> <p>6 is actually in use is significant in terms of</p> <p>7 safety or effectiveness?</p> <p>8 MR. COMBS: Object to the form, asked and</p> <p>9 answered.</p> <p>10 BY THE WITNESS:</p> <p>11 A. In my reading of literature, the type 1</p> <p>12 greater than 75 micron diameter pore size is right</p> <p>13 now the optimal mesh to use in a patient. Outside</p> <p>14 of that, I don't know what you're asking.</p> <p>15 MR. SLATER: Move to strike.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. I didn't ask any questions about Amid</p> <p>18 type 1. I will, I promise, in a couple minutes.</p> <p>19 But I didn't ask about that. I will try my</p> <p>20 question again.</p> <p>21 Am I correct that you do not hold</p> <p>22 yourself out as an expert with regard to any</p> <p>23 implications -- rephrase.</p> <p>24 Am I correct that you do not hold</p> <p>25 yourself out as an expert with regard to whether a</p>	<p style="text-align: right;">Page 57</p> <p>1 A. Well, I -- we want to place the 75</p> <p>2 micron pore size --</p> <p>3 Q. I didn't ask you about 75.</p> <p>4 A. -- without undue tension.</p> <p>5 MR. COMBS: Right now we are not going to do</p> <p>6 this. Dr. Elser is --</p> <p>7 MR. SLATER: -- your expert continually</p> <p>8 obstruct this deposition by not answering a simple</p> <p>9 answer. All she wants to talk about is Amid type 1</p> <p>10 and I haven't asked any questions about it.</p> <p>11 MR. COMBS: We are going to start with a basic</p> <p>12 rule of civility that you're going to let me --</p> <p>13 MR. SLATER: I don't want to be lectured.</p> <p>14 MR. COMBS: I'm just telling you right</p> <p>15 now we'll just take a break. If you're not going</p> <p>16 to allow me to finish my statement or the witness</p> <p>17 to finish her statement, we're just going to quit.</p> <p>18 Now, you need to let the witness finish</p> <p>19 her answer. You can move to strike it if you don't</p> <p>20 like it. But don't interrupt her and don't</p> <p>21 interrupt me. I'm not interrupting you.</p> <p>22 MR. SLATER: Well, you are right now. You are</p> <p>23 interrupting the whole flow and killing time. You</p> <p>24 need to instruct your witness with all due</p> <p>25 respect -- it's my understanding Judge Eifert</p>

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<p style="text-align: right;">Page 58</p> <p>1 expects it -- that she needs to answer my questions 2 and not go off on talking points. 3 MR. COMBS: She has answered your question 4 multiple times. 5 MR. SLATER: She has not. It's very 6 frustrating because it's not being answered. I 7 haven't gotten one answer about 1 millimeter pore 8 size yet. 9 BY MR. SLATER: 10 Q. I'll do this. I'm going to do something 11 for you, Dr. Elser. Let me ask you this. 12 Do you think and are you forming 13 opinions based on the assumption that the only 14 standard for pore size that matters is whether or 15 not the pore size is Amid type 1, which is 75 16 microns? Is that true? 17 A. That is what's in the urogyne literature 18 and you asked about what pore size under tension, 19 which is different. So, I may have opinions on 20 that. But I -- I'd like you to be more specific in 21 your questioning about that. I imagine you're 22 going to ask me something else. 23 MR. SLATER: Move to strike. 24 BY MR. SLATER: 25 Q. Doctor, are you aware that Amid doesn't</p>	<p style="text-align: right;">Page 60</p> <p>1 that specific question? 2 MR. COMBS: Object to the form, asked and 3 answered. 4 BY THE WITNESS: 5 A. No, I may have opinions if you ask me a 6 question in a different way later. But right now, 7 no. 8 BY MR. SLATER: 9 Q. On the question I just asked you I'm 10 correct, you have no opinion on that question, 11 right? 12 MR. COMBS: Object to the form, asked and 13 answered. 14 BY THE WITNESS: 15 A. Same answer. 16 BY MR. SLATER: 17 Q. The answer is you have no opinions on 18 that specific question, correct? 19 A. At this time. 20 Q. Do you know what Ethicon internally 21 thought about the significance of whether or not 22 the pores in the Prolift would be greater than 23 1 millimeter when the mesh would be under tension 24 in actual use? 25 A. No.</p>
<p style="text-align: right;">Page 59</p> <p>1 think that his standard applies to the type of mesh 2 used in the Prolift? 3 A. No. 4 Q. If that's the truth, that would undercut 5 a portion of the basis for your opinions, wouldn't 6 it? 7 MR. COMBS: Object to the form. 8 BY THE WITNESS: 9 A. No, because other literature uses Amid's 10 classification in talking about mesh in the urogyne 11 and urology literature, not Dr. Amid himself. 12 BY MR. SLATER: 13 Q. Are you aware that they're using the 14 term wrong, in the wrong context because they don't 15 understand it? 16 MR. COMBS: Object to the form. 17 BY THE WITNESS: 18 A. No, I don't know what you mean by that. 19 BY MR. SLATER: 20 Q. Have you ever studied specifically the 21 question of whether or not a 1 millimeter pore size 22 under strain is of any significance with the 23 Prolift? 24 A. No. 25 Q. Am I accurate you have no opinions on</p>	<p style="text-align: right;">Page 61</p> <p>1 MR. COMBS: Object to the form. 2 BY MR. SLATER: 3 Q. You have no knowledge on that, right? 4 A. Correct. 5 Q. Would you defer to the scientists at 6 Ethicon with regard to that question? 7 MR. COMBS: Object to the form. 8 BY THE WITNESS: 9 A. Would I defer to them for its clinical 10 meaning? 11 BY MR. SLATER: 12 Q. Sure. Yes. 13 A. That -- I would consider that as part of 14 the information we would take into consideration. 15 Q. Have you read any articles that you 16 could point to as you sit here now that discuss the 17 significance of a 1 millimeter pore size in a mesh 18 for use in treating a prolapse? 19 A. Not that I can point to right now. 20 Q. If Ethicon internally thought that 21 caution should be used by a doctor in deciding 22 whether or not to use a Prolift with a patient, 23 should that information have been in the IFU? 24 MR. COMBS: Object to the form. 25 BY THE WITNESS:</p>

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<p style="text-align: right;">Page 62</p> <p>1 A. I'm sorry. Can you word it again.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. If Ethicon Medical Affairs, if any --</p> <p>4 rephrase.</p> <p>5 If someone in Ethicon Medical Affairs</p> <p>6 believed that caution needed to be taken by a</p> <p>7 doctor before using a Prolift in particular women,</p> <p>8 should that information have been put in the IFU?</p> <p>9 MR. COMBS: Object to the form.</p> <p>10 BY THE WITNESS:</p> <p>11 A. That seems very vague. So I'll say no.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. If -- if Ethicon Medical Affairs</p> <p>14 believed that caution should be used before putting</p> <p>15 a Prolift into a woman based on some fact about her</p> <p>16 background or her demographics or her age or her</p> <p>17 level of prolapse or something about her</p> <p>18 co-morbidities, anything like that that was</p> <p>19 specific that could be related to specific</p> <p>20 patients, should that information have been in the</p> <p>21 IFU so doctors would have that information in</p> <p>22 deciding what to offer their patients?</p> <p>23 MR. COMBS: Object to the form.</p> <p>24 BY THE WITNESS:</p> <p>25 A. No. And, again, I look to the IFU for</p>	<p style="text-align: right;">Page 64</p> <p>1 patient, I want to be aware of at least some</p> <p>2 literature knowing what to expect before I would</p> <p>3 implant it in a patient.</p> <p>4 MR. SLATER: Move to strike after the word</p> <p>5 "fact."</p> <p>6 BY MR. SLATER:</p> <p>7 Q. Are you aware one way or the other of</p> <p>8 whether doctors relied on the IFU to tell them each</p> <p>9 of the significant risks and complications known to</p> <p>10 Ethicon?</p> <p>11 A. No. And I've never met a doctor who</p> <p>12 I've discussed IFUs with that ever said they used</p> <p>13 an IFU as their sole source of information.</p> <p>14 MR. SLATER: Move to strike after the word</p> <p>15 "no."</p> <p>16 MR. COMBS: Adam, we have been going now for</p> <p>17 over an hour. Let's -- let's wrap up sometime in</p> <p>18 the next five minutes and take a break.</p> <p>19 MR. SLATER: You need a break?</p> <p>20 MR. COMBS: Well, sometime in the next five</p> <p>21 minutes.</p> <p>22 MR. SLATER: Okay.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. Doctor, do you have any information as</p> <p>25 to what level or grade of prolapse Ethicon</p>
<p style="text-align: right;">Page 63</p> <p>1 some specific product-related procedural steps and</p> <p>2 some information on product but not for all of the</p> <p>3 precautions. I look to the literature and</p> <p>4 experience and attending conferences for the full</p> <p>5 picture.</p> <p>6 BY MR. SLATER:</p> <p>7 Q. Well, you realize there is doctors who</p> <p>8 were using the Prolift who had not attended</p> <p>9 conferences where they were lectured about who the</p> <p>10 Prolift should be used for, right?</p> <p>11 A. Yes.</p> <p>12 Q. So, they couldn't be expected to have</p> <p>13 that information, right?</p> <p>14 MR. COMBS: Object to the form.</p> <p>15 BY THE WITNESS:</p> <p>16 A. The information is in the literature</p> <p>17 because material at conferences is published.</p> <p>18 There is access.</p> <p>19 BY MR. SLATER:</p> <p>20 Q. There are some physicians who don't read</p> <p>21 very much medical literature because they are busy</p> <p>22 clinical practitioners and don't read very much</p> <p>23 literature. That's a known fact, correct?</p> <p>24 A. That's a known fact. Now, whether -- I</p> <p>25 mean, as an implanter of a permanent mesh in a</p>	<p style="text-align: right;">Page 65</p> <p>1 internally believed the Prolift should be limited</p> <p>2 to the use of?</p> <p>3 A. No.</p> <p>4 Q. If Ethicon internally believed the</p> <p>5 Prolift should be limited to stage 3 and stage 4</p> <p>6 prolapse, you don't know about that, right?</p> <p>7 A. No, I think that's our call as surgeons</p> <p>8 to know what stage prolapse deserves or is a</p> <p>9 candidate for a mesh augmentation.</p> <p>10 MR. SLATER: Move to strike after the word</p> <p>11 "no."</p> <p>12 BY MR. SLATER:</p> <p>13 Q. Do you know what level of prolapse the</p> <p>14 inventors of the prolapse thought the Prolift</p> <p>15 should be used with?</p> <p>16 A. No.</p> <p>17 Q. Do you know whether the inventors of the</p> <p>18 Prolift ever indicated in anything they published</p> <p>19 whether or not they thought the Prolift was an</p> <p>20 appropriate treatment as a primary treatment for a</p> <p>21 sexually active woman?</p> <p>22 A. No.</p> <p>23 Q. Do you know whether Ethicon Medical</p> <p>24 Affairs thought that caution should be shown before</p> <p>25 the Prolift would be used in a sexually active</p>

17 (Pages 62 to 65)

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<p style="text-align: right;">Page 66</p> <p>1 woman?</p> <p>2 A. No.</p> <p>3 Q. If Ethicon Medical Affairs thought that</p> <p>4 caution should be used before the Prolift should be</p> <p>5 used in a sexually active woman and that was</p> <p>6 thought even before the Prolift first went on the</p> <p>7 market in March of 2005, you would agree that</p> <p>8 information should have been in the IFU, right?</p> <p>9 A. No.</p> <p>10 MR. COMBS: Object to the form.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. And in March of 2005, doctors didn't</p> <p>13 have extensive experience with the use of the</p> <p>14 Prolift or kits. This was very new. So, at that</p> <p>15 point if Ethicon knew about risks or complications</p> <p>16 or relative contraindications or that caution</p> <p>17 should be used or anything like that, at that time</p> <p>18 point it would have been important to put that</p> <p>19 information in the IFU because this was the early</p> <p>20 days of the use of the Prolift, correct?</p> <p>21 MR. COMBS: Object to the form.</p> <p>22 BY THE WITNESS:</p> <p>23 A. No, this is not -- there was caution</p> <p>24 that there should be surgeons familiar with pelvic</p> <p>25 reconstructive surgery and the use of permanent</p>	<p style="text-align: right;">Page 68</p> <p>1 A. No.</p> <p>2 Q. Did you assume that Ethicon is familiar</p> <p>3 with clinical data, whether published or</p> <p>4 unpublished, that could be significant to assessing</p> <p>5 the safety and effectiveness of the Prolift that</p> <p>6 they would have provided that to you so you could</p> <p>7 consider it?</p> <p>8 A. That's such a broad question.</p> <p>9 Q. What's broad about it?</p> <p>10 A. That they would give me a list that has</p> <p>11 comprehensive every single thing that they know</p> <p>12 might have happened to the Prolift?</p> <p>13 Q. It's not what I asked. So I will try it</p> <p>14 again.</p> <p>15 A. Okay. Let me try and listen better,</p> <p>16 then.</p> <p>17 Q. If Ethicon knew of a particular clinical</p> <p>18 study for which data was presented at an important</p> <p>19 medical meeting with regard to safety or efficacy</p> <p>20 of the Prolift, would you have liked to have seen</p> <p>21 that?</p> <p>22 MR. COMBS: Object to the form.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Yes, I would like to have seen it. I</p> <p>25 don't know that I would rely on everything that's</p>
<p style="text-align: right;">Page 67</p> <p>1 implants in the pelvis. That warning was in there.</p> <p>2 So, physicians familiar with pelvic</p> <p>3 reconstruction and the use of permanent implants</p> <p>4 should have -- would have the clinical knowledge of</p> <p>5 being wary of using this product in sexually active</p> <p>6 women if they felt that was a population that might</p> <p>7 or might not be used in.</p> <p>8 MR. SLATER: Move to strike after the word</p> <p>9 "no."</p> <p>10 We can take a break.</p> <p>11 MR. COMBS: Okay.</p> <p>12 THE VIDEOGRAPHER: Okay. The time is 11:50</p> <p>13 a.m., and we are going off the video record.</p> <p>14 MR. SLATER: Ten minutes.</p> <p>15 MR. COMBS: Yeah. Let's talk briefly about</p> <p>16 lunch.</p> <p>17 (WHEREUPON, a recess was had</p> <p>18 from 11:50 a.m. to 12:02 p.m.)</p> <p>19 THE VIDEOGRAPHER: The time is 12:02 p.m. and</p> <p>20 we are back on the video record.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. Doctor, in your report, there's the list</p> <p>23 of medical literature Ethicon provided you the list</p> <p>24 of. You didn't read all those articles and</p> <p>25 references, did you?</p>	<p style="text-align: right;">Page 69</p> <p>1 been presented at any meeting related to Prolift.</p> <p>2 MR. SLATER: Move to strike from "I don't</p> <p>3 know" going forward.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. Unless you would see such data, you</p> <p>6 couldn't assess whether or not it was significant</p> <p>7 to you in forming your opinions, correct?</p> <p>8 A. No, but it would be one piece to add to</p> <p>9 all of the knowledge and literature that we have in</p> <p>10 the -- I have considered.</p> <p>11 MR. SLATER: Move to strike after the word</p> <p>12 "no."</p> <p>13 BY MR. SLATER:</p> <p>14 Q. It's possible that there is clinical</p> <p>15 data you didn't see which if you saw it could</p> <p>16 change your opinions in this case. That's</p> <p>17 possible, right?</p> <p>18 A. Yes. It's possible, but I'm relying on</p> <p>19 lots of literature and clinical experience to form</p> <p>20 my opinions and I don't think --</p> <p>21 Q. Move to strike.</p> <p>22 A. -- there is any one article that is</p> <p>23 going to change my mind.</p> <p>24 MR. SLATER: Move to strike from "but"</p> <p>25 forward.</p>

18 (Pages 66 to 69)

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<p style="text-align: right;">Page 70</p> <p>1 BY MR. SLATER:</p> <p>2 Q. Did you deliberately not cite to</p> <p>3 articles that were unfavorable to the Prolift?</p> <p>4 A. Did I deliberately. I don't think I</p> <p>5 deliberately chose not to cite -- I didn't look at</p> <p>6 an article and say I don't want to cite this one.</p> <p>7 I looked for articles I knew of that had facts I</p> <p>8 wanted in my report.</p> <p>9 Q. Are you familiar with the article</p> <p>10 published in the American Journal of Obstetrics and</p> <p>11 Gynecology in February of 2014 where the first</p> <p>12 named author is Sara Abbott?</p> <p>13 A. Sara Abbott. I have heard of it, but I</p> <p>14 would need to look at it to answer any questions on</p> <p>15 it right now.</p> <p>16 Q. Have you read that article?</p> <p>17 A. I need to look at it to answer that</p> <p>18 question.</p> <p>19 Q. I don't see it listed anywhere in your</p> <p>20 report, so you have it there but you didn't list</p> <p>21 it?</p> <p>22 A. I don't have it here. I said I would</p> <p>23 need to look at it to answer it.</p> <p>24 Q. This is my question since I only get to</p> <p>25 depose you once for this case.</p>	<p style="text-align: right;">Page 72</p> <p>1 BY THE WITNESS:</p> <p>2 A. On the surface, yes.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. If Ethicon made claims about the mesh in</p> <p>5 the Prolift that Ethicon had no data to support,</p> <p>6 would that be wrongful?</p> <p>7 MR. COMBS: Object to the form.</p> <p>8 BY THE WITNESS:</p> <p>9 A. I'm having trouble answering this</p> <p>10 because I'm trying to imagine reading an IFU and</p> <p>11 knowing what was said about the mesh that didn't</p> <p>12 have claims to support it.</p> <p>13 Descriptions of procedures are -- in an</p> <p>14 IFU doesn't necessarily have data behind it</p> <p>15 necessarily. I don't know. I don't know what</p> <p>16 you're trying to ask really.</p> <p>17 Q. Are you aware of anything in the Prolift</p> <p>18 IFU as to which anyone in Ethicon had admitted</p> <p>19 there was not data to support the claim about the</p> <p>20 mesh? Are you aware of that occurring?</p> <p>21 A. No.</p> <p>22 Q. Are you aware of Ethicon in deposition</p> <p>23 testimony admitting anything about the mesh which</p> <p>24 is contrary to what was represented in the IFU?</p> <p>25 A. No.</p>
<p style="text-align: right;">Page 71</p> <p>1 As you sit here now did you read that</p> <p>2 article?</p> <p>3 A. My answer is I may have read it. I</p> <p>4 don't recall right now.</p> <p>5 Q. Do you recall as you sit here right now</p> <p>6 whether there was anything of significance in that</p> <p>7 article that could be significant to the opinions</p> <p>8 you've reached in this case?</p> <p>9 A. I don't recall. If you want us to pull</p> <p>10 it at the break, I will be happy to answer</p> <p>11 questions about it.</p> <p>12 Q. I don't want to pull it at the break</p> <p>13 because you didn't include it anywhere -- rephrase.</p> <p>14 You did not reference the Abbott article</p> <p>15 anywhere, correct?</p> <p>16 A. In this report, no.</p> <p>17 Q. If Ethicon said something in the IFU</p> <p>18 which Ethicon knew not to be true, would you agree</p> <p>19 that that would be wrongful?</p> <p>20 MR. COMBS: Object to the form.</p> <p>21 BY THE WITNESS:</p> <p>22 A. Yes, I think that would be strange.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. Well, would it be wrongful?</p> <p>25 MR. COMBS: Object to the form.</p>	<p style="text-align: right;">Page 73</p> <p>1 Q. If either of those things occurred,</p> <p>2 would you agree that would be a failure to provide</p> <p>3 adequate and appropriate warning to doctors about</p> <p>4 the Prolift?</p> <p>5 MR. COMBS: Object to the form.</p> <p>6 BY THE WITNESS:</p> <p>7 A. No.</p> <p>8 BY MR. SLATER:</p> <p>9 Q. So, it's okay for Ethicon -- rephrase.</p> <p>10 So, it's not a failure to warn even if</p> <p>11 Ethicon provided information about the mesh it knew</p> <p>12 to be unsupported or it made an affirmative</p> <p>13 representation about the mesh that it knew not to</p> <p>14 be true, that's okay with you?</p> <p>15 A. My answer is yes because I -- I'm</p> <p>16 imagining circumstances where one person -- such a</p> <p>17 big company, one person in the company said one</p> <p>18 thing that may not be clinically applicable to what</p> <p>19 pelvic reconstructive surgeons are using the mesh</p> <p>20 for.</p> <p>21 Q. You have absolutely no idea how Ethicon</p> <p>22 creates the IFU or how the information is put into</p> <p>23 the IFU, you have no idea, right?</p> <p>24 A. No, I don't.</p> <p>25 Q. You have no idea about who has to</p>

19 (Pages 70 to 73)

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<p>1 confirm the accuracy and the truthfulness of the</p> <p>2 information in the IFU before it's actually printed</p> <p>3 and put into the box. You have no idea on that,</p> <p>4 right?</p> <p>5 A. That's correct.</p> <p>6 Q. And just to be clear, it's acceptable to</p> <p>7 you if Ethicon -- rephrase. Withdrawn.</p> <p>8 I want to just go back to your report</p> <p>9 for a couple minutes. The last few pages of</p> <p>10 Attachment B. The third-to-last page, it says</p> <p>11 "Publicly Available." There are publicly available</p> <p>12 documents. Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Did you compile that list or was that</p> <p>15 compiled for you by counsel?</p> <p>16 A. I don't remember because I pulled most</p> <p>17 of these things and I don't recall if this was</p> <p>18 provided for me.</p> <p>19 Q. Are you relying on any of the materials</p> <p>20 on the "Publicly Available" list to form your</p> <p>21 opinions?</p> <p>22 A. They add to my opinions, yes.</p> <p>23 Q. Sorry. Say that again.</p> <p>24 A. Yes, I've read most of these and they</p> <p>25 would help form my opinion, yes.</p>	<p>1 patient population. So, it didn't make sense to me</p> <p>2 how a large-scale RCT was going to solve this</p> <p>3 question for me or for my patients.</p> <p>4 Q. Actually in your report you cited to the</p> <p>5 portion of the Committee Opinion 513 that said that</p> <p>6 the mesh kit should be used only in high-risk</p> <p>7 individuals for which other options are not</p> <p>8 available or appropriate. You agree with that</p> <p>9 conclusion?</p> <p>10 MR. COMBS: Object to the form.</p> <p>11 BY THE WITNESS:</p> <p>12 A. They should be -- they are -- that's one</p> <p>13 of the considerations taking in. I don't -- I</p> <p>14 object to "should be used." I don't know that I</p> <p>15 would agree with that.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. Well, you agree that the Prolift should</p> <p>18 only be used in women for whom other approaches and</p> <p>19 other alternative treatments are not reasonable</p> <p>20 options. Do you agree with that?</p> <p>21 MR. COMBS: Object to the form.</p> <p>22 BY THE WITNESS:</p> <p>23 A. No, because they may be reasonable</p> <p>24 options and a patient has a choice, has some input</p> <p>25 into what she chooses, one or the other, after</p>
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<p>1 Q. You're familiar with Committee Opinion</p> <p>2 513, the joint opinion of ACOG and AUGS, correct?</p> <p>3 A. Yes.</p> <p>4 Q. Was that of significance to you in</p> <p>5 forming your opinions in this case?</p> <p>6 A. It was part of what I used to form my</p> <p>7 opinions, yes.</p> <p>8 Q. And you feel that the conclusions found</p> <p>9 in that committee opinion are applicable to the</p> <p>10 Prolift, correct?</p> <p>11 A. For the most part.</p> <p>12 Q. What do you do, do you pick the ones</p> <p>13 that -- well, rephrase.</p> <p>14 When you say "for the most part," which</p> <p>15 ones aren't applicable to the Prolift? Which</p> <p>16 conclusions in 513 are not applicable?</p> <p>17 A. Okay. I need to open it in front of me</p> <p>18 to answer specifically, but my biggest -- the fact</p> <p>19 that AUGS and ACOG put it out doesn't mean I agree</p> <p>20 with everything that they said.</p> <p>21 So, my biggest complaint out of that</p> <p>22 document was the need to have a randomized</p> <p>23 controlled trial of a vaginal mesh kit to a native</p> <p>24 tissue repair because to me I'm not necessarily</p> <p>25 going to use those two approaches on the same</p>	<p>1 being counseled.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. If one were to apply the Committee</p> <p>4 Opinion 513 patient selection criteria, Ms. Bellew</p> <p>5 would not meet that criteria and would be excluded,</p> <p>6 correct?</p> <p>7 A. No.</p> <p>8 Q. I'm not correct?</p> <p>9 A. Correct. Right. My -- she did not meet</p> <p>10 the criteria to have vaginal mesh placed?</p> <p>11 Q. That's not my question. Let me ask</p> <p>12 this: Dianne Bellew was an acceptable candidate to</p> <p>13 have nothing done. That was one of her options,</p> <p>14 right?</p> <p>15 A. Right.</p> <p>16 Q. Dianne Bellew was an acceptable</p> <p>17 candidate for an anterior colporrhaphy simply with</p> <p>18 native tissue and suture, correct?</p> <p>19 A. Correct.</p> <p>20 Q. Dianne Bellew was not a high-risk</p> <p>21 individual for whom treatments other than the</p> <p>22 Prolift were not available or indicated, correct?</p> <p>23 A. No. She has emphysema.</p> <p>24 Q. She what?</p> <p>25 A. She has emphysema and she's a smoker.</p>

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<p>1 MR. SLATER: Move to strike.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. Ms. Bellew, if you apply -- rephrase.</p> <p>4 If you applied Committee Opinion 513 to</p> <p>5 Ms. Bellew as she first went to Dr. DeHase, she's</p> <p>6 not one of those high-risk individuals for whom</p> <p>7 procedures other than the Prolift would not have</p> <p>8 been available options, correct?</p> <p>9 A. No, not necessarily. She has -- she's a</p> <p>10 smoker with emphysema.</p> <p>11 Q. And which procedure -- well, rephrase</p> <p>12 that.</p> <p>13 The fact that Ms. Bellew was a smoker</p> <p>14 would not exclude her from being a candidate for</p> <p>15 anterior colporrhaphy with sutures, correct?</p> <p>16 A. Well, it's certainly someone I would</p> <p>17 counsel. She's at higher risk than a non-smoker</p> <p>18 without emphysema for recurrence, an early</p> <p>19 recurrence after a native tissue repair.</p> <p>20 Q. Ms. Bellew never had a recurrence, did</p> <p>21 she?</p> <p>22 A. No.</p> <p>23 Q. The only time that sutures had to be</p> <p>24 placed was after Dr. DeHase realized after she</p> <p>25 removed a significant amount of mesh from the left</p>	<p>1 smoking as a risk factor for erosion exposure.</p> <p>2 MR. SLATER: Move to strike.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. The IFU that was in effect when</p> <p>5 Ms. Bellew had her surgery did not mention smoking</p> <p>6 as a risk for anything, correct?</p> <p>7 A. I would have to look at it to say which</p> <p>8 IFU contained that.</p> <p>9 Q. You don't know as you sit here now, do</p> <p>10 you?</p> <p>11 A. Right, I don't recall that one.</p> <p>12 Q. Ms. Bellew had granulation tissue about</p> <p>13 a month or so after the surgery and that was</p> <p>14 treated by Dr. DeHase, correct?</p> <p>15 A. Yes.</p> <p>16 Q. The mesh was likely a contributing</p> <p>17 factor to the development of that granulation</p> <p>18 tissue, correct?</p> <p>19 A. I don't know.</p> <p>20 Q. You don't have an opinion one way or the</p> <p>21 other on that?</p> <p>22 A. No, could happen at the site of the</p> <p>23 suture. It happens more often in smokers. So, we</p> <p>24 don't know if the mesh contributed.</p> <p>25 Q. I just want to know you're not forming</p>
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<p>1 arm that there was now a defect that needed to be</p> <p>2 shored up so that what was now a stage 1 prolapse</p> <p>3 wouldn't become worse, that's the only time sutures</p> <p>4 needed to be used, correct?</p> <p>5 A. In order to fix a prolapse repair you're</p> <p>6 saying?</p> <p>7 Q. Yes.</p> <p>8 A. Yes. And it would be really great if we</p> <p>9 could look at every patient and say you are going</p> <p>10 to recur if I use native tissue or you are not. We</p> <p>11 can only look at risk factors and tissue quality.</p> <p>12 MR. SLATER: Move to strike from "and"</p> <p>13 forward.</p> <p>14 BY MR. SLATER:</p> <p>15 Q. Let me ask you this about smoking. Do</p> <p>16 you know that Ethicon was advertising and marketing</p> <p>17 the Prolift to smokers?</p> <p>18 A. No.</p> <p>19 Q. Do you know that at the time Ms. Bellew</p> <p>20 was consented for the procedure there was no</p> <p>21 warning in the IFU as to smoking creating any</p> <p>22 increased risk for her?</p> <p>23 A. I would have to look at that particular</p> <p>24 IFU. But I would like to make a distinction</p> <p>25 between smoking as a risk factor for recurrence and</p>	<p>1 an opinion on that, correct?</p> <p>2 MR. COMBS: Object.</p> <p>3 BY THE WITNESS:</p> <p>4 A. A suture or mesh is a risk factor for</p> <p>5 granulation tissue.</p> <p>6 BY MR. SLATER:</p> <p>7 Q. So, it's possible that the mesh</p> <p>8 contributed to the granulation tissue, correct?</p> <p>9 A. It's possible.</p> <p>10 Q. Beyond that, you're not forming an</p> <p>11 opinion with regard to the cause of the granulation</p> <p>12 tissue, correct?</p> <p>13 A. Right. We don't know what caused it.</p> <p>14 Q. In 2011 and 2012 Dr. DeHase operated</p> <p>15 three times on Ms. Bellew, correct?</p> <p>16 A. Say the dates again.</p> <p>17 Q. In 2011 and 2012 Dr. DeHase operated</p> <p>18 three times on Ms. Bellew, correct?</p> <p>19 A. Yeah.</p> <p>20 Q. Each time Dr. DeHase found what she</p> <p>21 described as sclerosed, hardened mesh, correct?</p> <p>22 A. Yes.</p> <p>23 Q. You would agree that is mesh that had</p> <p>24 scar plates across it that was creating contraction</p> <p>25 and hardening of the mesh, correct?</p>

21 (Pages 78 to 81)

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<p style="text-align: right;">Page 82</p> <p>1 MR. COMBS: Object to form.</p> <p>2 BY THE WITNESS:</p> <p>3 A. I'm not sure what you mean by scar</p> <p>4 plates, but there certainly was scarring and</p> <p>5 fibrosis in the area of the mesh.</p> <p>6 BY MR. SLATER:</p> <p>7 Q. Do you know what the term "scar plate"</p> <p>8 means?</p> <p>9 A. No.</p> <p>10 Q. You've never seen that term?</p> <p>11 A. I've seen it, but I don't know the</p> <p>12 definition.</p> <p>13 Q. Do you know whether the term</p> <p>14 "scar plate" had any significance for Ethicon</p> <p>15 internally among its doctors and scientists?</p> <p>16 A. No.</p> <p>17 Q. The hardening and the formation of the</p> <p>18 scar tissue -- well, rephrase.</p> <p>19 You would agree that the mesh through</p> <p>20 that process of the scar tissue and fibrosis</p> <p>21 forming on the mesh would have also been</p> <p>22 accompanied by contraction of the mesh, correct?</p> <p>23 A. It can be, yeah.</p> <p>24 Q. I'm sorry?</p> <p>25 A. Yes, it can be.</p>	<p style="text-align: right;">Page 84</p> <p>1 BY THE WITNESS:</p> <p>2 A. Yes, most likely because it was found in</p> <p>3 the area of the mesh arm, but we can see --</p> <p>4 BY MR. SLATER:</p> <p>5 Q. Dr. DeHase confirmed clinically</p> <p>6 Ms. Bellew was feeling pain and tenderness in the</p> <p>7 area where the mesh was contracted and sclerosed,</p> <p>8 correct?</p> <p>9 A. Yes, she felt on exam that the area of</p> <p>10 sclerosis reproduced pain.</p> <p>11 Q. And you in your opinion would agree that</p> <p>12 it's more likely than not the contracted sclerosed</p> <p>13 mesh was causing pain and tenderness for</p> <p>14 Ms. Bellew, correct?</p> <p>15 A. Yes.</p> <p>16 Q. And you would agree with me that each of</p> <p>17 the surgeries that were performed by Dr. DeHase in</p> <p>18 2011 and 2012, the three mesh excision surgeries,</p> <p>19 occurred and were caused by the fact that the</p> <p>20 Prolift was in Ms. Bellew's body, had developed the</p> <p>21 contraction and the sclerosis, was causing her pain</p> <p>22 and needed to have the mesh removed, correct?</p> <p>23 MR. COMBS: Object to the form.</p> <p>24 BY THE WITNESS:</p> <p>25 A. Yes. It was most likely that she was --</p>
<p style="text-align: right;">Page 83</p> <p>1 Q. In this case it's more likely than not</p> <p>2 that Ms. Bellew's Prolift mesh was contracted,</p> <p>3 correct?</p> <p>4 A. At that site where it was felt to be</p> <p>5 sclerosed, yes.</p> <p>6 Q. The contraction and the sclerosis and</p> <p>7 the hardening of the mesh that was removed from</p> <p>8 Dr. DeHase, that occurred due to the fact that the</p> <p>9 mesh was in Ms. Bellew's body and this occurred due</p> <p>10 to the Prolift mesh, correct?</p> <p>11 MR. COMBS: Object to the form.</p> <p>12 BY THE WITNESS:</p> <p>13 A. I just want to make one little</p> <p>14 correction because I don't know how picky you are,</p> <p>15 but you said "removed from Dr. DeHase" and I'm</p> <p>16 going to assume you mean "by Dr. DeHase."</p> <p>17 Q. Yes.</p> <p>18 A. Okay, thanks, because I don't know</p> <p>19 anything about Dr. DeHase having surgery.</p> <p>20 Can you ask me again.</p> <p>21 Q. Sure. The contraction and the fibrosis</p> <p>22 and the hardened scar tissue forming across the</p> <p>23 mesh, that occurred and was caused by the Prolift</p> <p>24 being in Ms. Bellew's body, correct?</p> <p>25 MR. COMBS: Object to the form.</p>	<p style="text-align: right;">Page 85</p> <p>1 had pain at the area of the mesh arm where there</p> <p>2 was some fibrosis and scarring and the treatment --</p> <p>3 part of the treatment was removal of that arm of</p> <p>4 the mesh.</p> <p>5 BY MR. SLATER:</p> <p>6 Q. Dr. DeHase testified that she believes</p> <p>7 that this is a progressive situation where the</p> <p>8 fibrosis and the contraction continues to occur</p> <p>9 with the Prolift mesh. You would agree with that,</p> <p>10 correct?</p> <p>11 MR. COMBS: Object to the form.</p> <p>12 BY THE WITNESS:</p> <p>13 A. No, I would not.</p> <p>14 BY MR. SLATER:</p> <p>15 Q. You're saying it's possible it is, it's</p> <p>16 possible it's not. You don't know at this point,</p> <p>17 correct?</p> <p>18 MR. COMBS: Objection to form.</p> <p>19 BY THE WITNESS:</p> <p>20 A. I would say that no, it is likely not.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. Well, there is a possibility that there</p> <p>23 is going to be further contraction and hardening</p> <p>24 and sclerosis of the mesh that could cause more</p> <p>25 pain and need -- and cause more surgery in the</p>

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<p style="text-align: right;">Page 86</p> <p>1 future. That's possible, right?</p> <p>2 MR. COMBS: Object to the form.</p> <p>3 BY THE WITNESS:</p> <p>4 A. It's possible but unlikely.</p> <p>5 MR. SLATER: Move to strike from "but"</p> <p>6 forward.</p> <p>7 Just checking my notes to try to move</p> <p>8 through this a little quicker.</p> <p>9 BY MR. SLATER:</p> <p>10 Q. You would agree with me that the</p> <p>11 complications that were treated by Dr. DeHasse on</p> <p>12 July 27, 2011, on October 6, 2011 and July 12,</p> <p>13 2012, the three excision surgeries, that those</p> <p>14 complications were due to the Prolift, correct?</p> <p>15 MR. COMBS: Object to the form.</p> <p>16 BY THE WITNESS:</p> <p>17 A. As it pertains to excising the fibrosed</p> <p>18 area of the mesh, because she also had abdominal</p> <p>19 surgery on the 12th, in July of '12.</p> <p>20 BY MR. SLATER:</p> <p>21 Q. I'm talking about with regard to the</p> <p>22 mesh.</p> <p>23 A. Yes, she had some -- she had fibrosis</p> <p>24 around the site of the left mesh arm that was</p> <p>25 excised.</p>	<p style="text-align: right;">Page 88</p> <p>1 have two issues vaginally at this point, some</p> <p>2 scarring in her vagina from the surgeries and</p> <p>3 myofascial pain in her pelvic floor. Do I</p> <p>4 understand that correctly?</p> <p>5 A. Yes.</p> <p>6 Q. And am I correct that those would both</p> <p>7 be causally related to the Prolift being in her</p> <p>8 body and the multiple surgeries to remove portions</p> <p>9 of the mesh?</p> <p>10 A. No.</p> <p>11 Q. Well, certainly those surgeries and the</p> <p>12 presence of the Prolift would contribute to the</p> <p>13 scarring in the vagina that causes discomfort and</p> <p>14 pain to Ms. Bellew, correct?</p> <p>15 MR. COMBS: Object to the form.</p> <p>16 BY THE WITNESS:</p> <p>17 A. No. My opinion is that the myofascial</p> <p>18 disorder is most likely causing her pain at this</p> <p>19 point and that's -- until that's treated we can't</p> <p>20 comment on how much the scar is contributing.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. So, with regard to the scarring in</p> <p>23 Ms. Bellew's vagina, you're not forming an opinion</p> <p>24 one way or the other as to whether or not that's</p> <p>25 causing her pain currently?</p>
<p style="text-align: right;">Page 87</p> <p>1 Q. And you'd agree those surgeries were</p> <p>2 indicated and appropriate, correct?</p> <p>3 A. Yes.</p> <p>4 Q. And you'd agree that the indication for</p> <p>5 the surgery, at least in part, was that this</p> <p>6 hardened, sclerosed mesh was causing pain for</p> <p>7 Ms. Bellew and that was a part of the appropriate</p> <p>8 indication for those three surgeries, correct?</p> <p>9 A. Yes. That's part of the treatment for</p> <p>10 that problem.</p> <p>11 Q. You would agree with me that there was a</p> <p>12 chronic foreign body reaction to the Prolift mesh</p> <p>13 in Ms. Bellew's body, correct?</p> <p>14 A. I don't comment on that because I did</p> <p>15 not read the pathology report.</p> <p>16 Q. So, you have no opinion one way or the</p> <p>17 other on that question?</p> <p>18 A. That's correct.</p> <p>19 Q. Are you aware of whether or not the</p> <p>20 Prolift causes a chronic foreign body reaction in a</p> <p>21 woman's body?</p> <p>22 A. Yes, as far as I know, foreign bodies</p> <p>23 cause foreign body reaction for the most part.</p> <p>24 Q. If I read your report correctly, it's my</p> <p>25 understanding that you believe that Ms. Bellew may</p>	<p style="text-align: right;">Page 89</p> <p>1 A. I will say that, yes, it was an area</p> <p>2 around the left sulcus as described by Dr. Elliott</p> <p>3 as being tender on exam but he doesn't describe a</p> <p>4 scar there.</p> <p>5 And even if there is a scar there, if</p> <p>6 there's hypertonic muscles in that area pulling on</p> <p>7 the scar, the scar might be tender, but not the</p> <p>8 primary source of pain, because until you address</p> <p>9 that muscle tone we can't tell if the scar is going</p> <p>10 to be a problem or not.</p> <p>11 Q. So, with regard to the scarring in the</p> <p>12 vagina, you're not giving an opinion at this point</p> <p>13 as to whether or not that's contributing to</p> <p>14 Ms. Bellew's complaints of pain in her vaginal</p> <p>15 area, correct?</p> <p>16 A. No, at this point I think her myofascial</p> <p>17 problem is her primary problem and she -- of course</p> <p>18 she has a scar in her vagina. She's had surgery.</p> <p>19 I believe it's less likely --</p> <p>20 Q. With regard to the myofascial pain, that</p> <p>21 is causally related to the fact that the Prolift</p> <p>22 was in Ms. Bellew's body, it had to be removed with</p> <p>23 three operations, correct?</p> <p>24 A. I don't -- no, I don't agree with that.</p> <p>25 Q. Certainly the fact that the Prolift was</p>

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<p style="text-align: right;">Page 90</p> <p>1 in Ms. Bellew's body, the fact that it had this 2 inflammatory reaction, it was hardened, contracted 3 and then three operations were performed through 4 the vagina to remove mesh, that would be a 5 contributing factor contributing to the myofascial 6 pain, correct? 7 MR. COMBS: Object to the form. 8 BY THE WITNESS: 9 A. Correct, in that it may contribute to 10 the pain but she had sclerosing and fibrosis of one 11 particular area of the mesh. A very limited 12 surgery was performed to remove that area. That 13 area no longer has any sclerosing or mesh palpable. 14 And she had preexisting dyspareunia before the 15 surgery and she has chronic myofascial pain in many 16 other parts of her body. 17 So, I don't know what was preexisting, 18 what was caused by having a hysterectomy or what to 19 what degree having had a prolapse surgery or mesh 20 placed contributed to her myofascial pain that she 21 experiences now. 22 Q. If I understand your answer, the Prolift 23 being in Ms. Bellew's body and the three operations 24 to remove it could be a contributing factor, one 25 contributing factor to the development of the</p>	<p style="text-align: right;">Page 92</p> <p>1 Ms. Bellew went through of three operations to 2 remove portions of the mesh going through those 3 three operations contributed to the development of 4 the myofascial pain syndrome? 5 A. No. 6 Q. You're saying it's possible that it 7 contributed but you can't say more than that? 8 A. Correct. 9 Q. Ms. Bellew had no findings of myofascial 10 pain before the Prolift surgery, correct? 11 A. No. 12 Q. I'm correct, right? 13 A. No, you're not correct. 14 Q. Ms. Bellew -- new question. 15 Ms. Bellew had no symptoms, complaints 16 or findings of myofascial pain or spasm in her 17 pelvic floor before the surgery, correct? I'm only 18 talking about the pelvic floor now before the 19 Prolift. 20 A. No, the answer is we don't know. She 21 had complaints of pelvic pain, abdominal pain; and 22 I don't see an assessment of the pelvic muscle tone 23 on the initial evaluation so I don't know what she 24 had. 25 Q. The only indication of any pelvic or</p>
<p style="text-align: right;">Page 91</p> <p>1 myofascial pain in her pelvic floor. Fair 2 statement? 3 MR. COMBS: Object to form. 4 BY THE WITNESS: 5 A. Yes. 6 BY MR. SLATER: 7 Q. It's certainly likely that it's 8 contributing to some effect, some extent, correct? 9 A. At this point I don't know because she 10 had the offending area removed. 11 Q. Well, it's certainly likely that the 12 Prolift being in her body and the three operations 13 to excise the contracted mesh contributed to the 14 development of the myofascial pain condition, 15 correct? 16 A. No, except any pelvic surgery can cause 17 a flare of myofascial pain and I can't say that the 18 fact that she has Prolift there now with the 19 sclerosed area removed is a contributing factor at 20 this point. 21 MR. SLATER: Move to strike. 22 That's not my question. Let me just try 23 to ask it better. 24 BY MR. SLATER: 25 Q. Would you agree with me that the course</p>	<p style="text-align: right;">Page 93</p> <p>1 vaginal pain or discomfort before the Prolift 2 surgery was -- you referred to it in Dr. Leano's 3 record, that when she went to the emergency room 4 last week, and this is May 20, 2009, when she went 5 to the emergency room last week with complaints 6 about abdominal and vaginal pain she was told her 7 bladder had fallen. That's the one note, correct? 8 MR. COMBS: Object to form. 9 BY THE WITNESS: 10 A. That's the one note in the medical 11 records, correct. 12 BY MR. SLATER: 13 Q. And what that's referring to is when the 14 cystocele formed and the -- and Ms. Bellew first 15 became aware of it, she complained of this causing 16 her pain and discomfort and this abnormal sensation 17 where it said it felt like she had a tampon 18 dropping into her vagina, correct? 19 A. Yes, but I -- it's very unlikely that a 20 second degree cystocele causes pain that would take 21 someone to the emergency room. So it's very 22 possible that she had myofascial pain that was not 23 assessed. That's not something that typically an 24 ER doctor would ever address on pelvic exam. 25 So, they saw a cystocele and told her</p>

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<p style="text-align: right;">Page 94</p> <p>1 that was her finding because that would be the 2 level of evaluation expected from an emergency room 3 physician. 4 So, I still don't have anyone that's 5 told us what is the state of her pelvic muscles 6 prior to that. She has told us in her testimony 7 that she had hints at dyspareunia before the 8 surgery. 9 MR. SLATER: Move to strike from "but" 10 forward. 11 BY MR. SLATER: 12 Q. You don't -- rephrase. 13 Do you know whether Ms. Bellew went to 14 the emergency room because she was concerned about 15 this sensation of something dropping into her 16 vagina? 17 A. No. 18 Q. On June 15, 2009 Ms. Bellew saw 19 Dr. DeHasse for the first time, right? 20 A. Right. 21 Q. And she reported that she has been 22 feeling like she has a falling tampon. She went to 23 see Dr. Leano who explained she has a fallen 24 bladder. Wants surgical correction. Admits to 25 frequency and nocturia. No incontinence. Is not</p>	<p style="text-align: right;">Page 96</p> <p>1 change. 2 MR. SLATER: All right. Tell me at five and 3 at three. 4 THE VIDEOGRAPHER: Okay. 5 BY THE WITNESS: 6 A. I'm almost with you. Okay. And you 7 were looking for a June visit? 8 BY MR. SLATER: 9 Q. Looking at June 15, 2009, when 10 Ms. Bellew first went to Dr. DeHasse. Got that? 11 A. I am real close. I'm in June. June 20 12 is Leano. May 27 -- no, I don't have that page. 13 Sorry. I mean I know I have it here somewhere. 14 Q. You don't have -- do you have 15 Dr. DeHasse's records? 16 A. Yeah, yeah. I'm sorry. I was just 17 having trouble getting on the same page with you. 18 Q. Do you have it there? 19 A. I'm flipping as fast as I can. I'm 20 sorry. I know I'm using up all your tape space. 21 June 20, Dr. DeHasse. 22 MR. COMBS: June 15. 23 BY MR. SLATER: 24 Q. June 15, Dr. DeHasse. 25 A. You want June 15. Okay.</p>
<p style="text-align: right;">Page 95</p> <p>1 currently sexually active. Lives at home with her 2 daughter and grandchildren. That's what was 3 recorded according to the record, right? 4 A. Did you say no incontinence? 5 Q. It says no incontinence right in the 6 record. Correct? 7 A. Okay. But in another record I think 8 Dr. Leano, she said she does leak with cough. 9 MR. SLATER: Move to strike. 10 BY MR. SLATER: 11 Q. Doctor, what I just read to you from the 12 history -- rephrase. 13 What I described to you is the History 14 of Present Illness that's documented in 15 Dr. DeHasse's record for June 15, 2009, correct? 16 A. I would like to pull the record in front 17 of me. 18 Q. Go ahead. 19 A. Okay. Disconnect for a second. 20 THE VIDEOGRAPHER: Sure. 21 Excuse me, Counselor Slater. This is 22 Milo, the videographer. 23 MR. SLATER: Hi. 24 THE VIDEOGRAPHER: Hi. We have about ten 25 minutes of usable tape left. Then I have to</p>	<p style="text-align: right;">Page 97</p> <p>1 Q. On June 15, 2009, when Ms. Bellew saw 2 Dr. DeHasse, she told her she has been feeling like 3 she has a falling tampon. Dr. Leano had explained 4 she has a fallen bladder. That's a cystocele, 5 correct? 6 A. Right. 7 Q. She wanted surgical correction. She 8 admits to frequency and nocturia, no incontinence. 9 That's what was reported, right? 10 A. Okay. 11 Q. Is not currently sexually active, lives 12 at home with her daughter and grandchildren. 13 That's what's reported in the history, right? 14 A. That's what she said. 15 Q. Ms. Bellew reported no pain in her 16 pelvis or vagina when she saw Dr. DeHasse on 17 June 15, 2009, correct? 18 MR. COMBS: Object to the form. 19 BY THE WITNESS: 20 A. I'm sorry. I really -- I really 21 apologize, but I just can't find that page. So... 22 Q. Dr. Elser. 23 A. Yeah. 24 Q. Do you agree with me -- 25 MR. COMBS: Adam, Adam, just here. We have</p>

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<p style="text-align: right;">Page 98</p> <p>1 got the page for her. So we'll give that --</p> <p>2 THE WITNESS: Thanks.</p> <p>3 MR. COMBS: -- to Dr. Elser.</p> <p>4 THE WITNESS: Sorry about that. Okay.</p> <p>5 BY MR. SLATER:</p> <p>6 Q. Dr. Elser.</p> <p>7 A. Yes.</p> <p>8 Q. On June 15, 2009, when Ms. Bellew went</p> <p>9 to Dr. DeHasse, she was not complaining of pelvic</p> <p>10 or vaginal pain, correct?</p> <p>11 A. She went to the ER last week with</p> <p>12 complaint of abdominal vaginal pain.</p> <p>13 Q. Where does it say that?</p> <p>14 A. History of Present Illness.</p> <p>15 Q. Which record are you looking at? I'm</p> <p>16 looking at Dr. DeHasse's record of June 15, 2009.</p> <p>17 A. Okay. I'm sorry. I had Dr. Leano's</p> <p>18 note.</p> <p>19 Q. Please.</p> <p>20 A. Okay. We're together now.</p> <p>21 MR. SLATER: Move to strike.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. On June 15, 2009, when Ms. Bellew went</p> <p>24 to Dr. DeHasse, she was not complaining of any</p> <p>25 pelvic or vaginal pain, correct?</p>	<p style="text-align: right;">Page 100</p> <p>1 Q. In the exam section of this record,</p> <p>2 Dr. DeHasse does not document finding any pelvic</p> <p>3 floor muscle spasm, correct?</p> <p>4 A. That's correct.</p> <p>5 Q. And there are no complaints of</p> <p>6 tenderness on the exam of the vagina or pelvis,</p> <p>7 there is nothing documented, correct?</p> <p>8 A. That's right.</p> <p>9 Q. Based on the medical records, the only</p> <p>10 notations of spasm or pain in the pelvic floor</p> <p>11 comes after the Prolift surgery, correct?</p> <p>12 A. Right, except I don't know what caused</p> <p>13 her pain when she went to the ER.</p> <p>14 MR. SLATER: Move to strike after the word</p> <p>15 "right."</p> <p>16 BY MR. SLATER:</p> <p>17 Q. When a woman has prolapse, she can feel</p> <p>18 discomfort especially when it first happens and it</p> <p>19 can be described as discomfort, it can be described</p> <p>20 as pain, it can be described multiple ways because</p> <p>21 it's a new and troubling sensation for the woman,</p> <p>22 correct?</p> <p>23 MR. COMBS: Object to form.</p> <p>24 BY THE WITNESS:</p> <p>25 A. It could be, yes.</p>
<p style="text-align: right;">Page 99</p> <p>1 A. Correct.</p> <p>2 Q. She said she has a sensation like she</p> <p>3 had a falling tampon, correct?</p> <p>4 A. Right.</p> <p>5 Q. Dr. DeHasse performed an examination,</p> <p>6 correct?</p> <p>7 A. Yes.</p> <p>8 Q. She found a grade 2 cystocele, right?</p> <p>9 A. Yes.</p> <p>10 Q. She found no evidence, according to the</p> <p>11 exam and the documentation, of any pain --</p> <p>12 rephrase.</p> <p>13 Dr. DeHasse found no indication on her</p> <p>14 exam of any myofascial pain or pelvic floor myalgia</p> <p>15 or hypertonicity or pelvic floor muscle spasm on</p> <p>16 that exam on June 15, 2009, correct?</p> <p>17 A. The muscle tone is not -- is not</p> <p>18 commented on. Whether she could have had laxity at</p> <p>19 rest, whether she had hypertonicity, whether the</p> <p>20 muscles were tender or whether she could do a</p> <p>21 voluntary pelvic floor contraction.</p> <p>22 THE VIDEOGRAPHER: Counselor Slater, we have</p> <p>23 five minutes left.</p> <p>24 MR. SLATER: All right. Move to strike.</p> <p>25 BY MR. SLATER:</p>	<p style="text-align: right;">Page 101</p> <p>1 BY MR. SLATER:</p> <p>2 Q. In fact, Dr. Leano wrote that Ms. Bellew</p> <p>3 had pain when she went to the emergency room but we</p> <p>4 don't know if that's Ms. Bellew's word or</p> <p>5 Dr. Leano's word, right?</p> <p>6 A. Right.</p> <p>7 Q. Did you look at the emergency room</p> <p>8 record to see what was described in that record?</p> <p>9 A. I don't recall that.</p> <p>10 MR. SLATER: All right. I think now is</p> <p>11 probably a good time if you want to get lunch.</p> <p>12 Let's go off the video and switch tapes.</p> <p>13 MR. COMBS: Okay.</p> <p>14 THE VIDEOGRAPHER: The time is 12:43 p.m.</p> <p>15 This is the end of Tape 1 and we are going off the</p> <p>16 video record.</p> <p>17 (WHEREUPON, a recess was had</p> <p>18 from 12:43 to 1:25 p.m.)</p> <p>19 THE VIDEOGRAPHER: The time is 1:25 p.m. This</p> <p>20 is the beginning of Tape 2 and we are back on the</p> <p>21 video record.</p> <p>22 MR. SLATER: Okay.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. I just want to establish one thing,</p> <p>25 Dr. Elser. You've worked as a consultant for</p>

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<p style="text-align: right;">Page 102</p> <p>1 Ethicon, correct?</p> <p>2 A. Yes.</p> <p>3 Q. Paid consultant?</p> <p>4 MR. COMBS: You may have interrupted him. So</p> <p>5 if you could just answer.</p> <p>6 BY THE WITNESS:</p> <p>7 A. I'm sorry. Okay. I'm sorry. Did I</p> <p>8 interrupt the question?</p> <p>9 BY MR. SLATER:</p> <p>10 Q. I don't know. I will ask it again.</p> <p>11 You've worked as a paid consultant for</p> <p>12 the Ethicon, correct?</p> <p>13 A. Yes.</p> <p>14 Q. When did you start doing that work?</p> <p>15 I'm not going to get into a lot of</p> <p>16 detail, but I just want to establish some</p> <p>17 parameters. Let me ask it again.</p> <p>18 When did you start working as a paid</p> <p>19 consultant with Ethicon?</p> <p>20 A. Without knowing the exact year when we</p> <p>21 started doing TVT preceptorships.</p> <p>22 Q. Once you began to work as a consultant</p> <p>23 with Ethicon, did you continue doing so right up</p> <p>24 until the present?</p> <p>25 A. No, and in the way it worked was we</p>	<p style="text-align: right;">Page 104</p> <p>1 would not be -- act as a consultant when I served</p> <p>2 on a committee with ACOG.</p> <p>3 Q. When did you serve on a committee with</p> <p>4 ACOG?</p> <p>5 A. I think it was '08 to '11. But the --</p> <p>6 the rules changed in the middle of that, toward the</p> <p>7 end of that term with regards to relationship with</p> <p>8 industry. So, it did not cover my whole time</p> <p>9 there.</p> <p>10 Q. What changed?</p> <p>11 A. That committee members could not have</p> <p>12 a -- do active paid consulting with industry while</p> <p>13 they were on a committee.</p> <p>14 So, I'm sorry, for my CV, I was on that</p> <p>15 committee 2009 to 2012. Usually --</p> <p>16 Q. You were under contract with Ethicon</p> <p>17 during part of that time, though, as a paid</p> <p>18 consultant, correct?</p> <p>19 A. Well, it's not like I drew a regular</p> <p>20 paycheck. That contract covered me if I accepted a</p> <p>21 one-time event on a case-by-case basis during the</p> <p>22 period of that contract. So, it was toward the end</p> <p>23 of my term on that committee that these new rules</p> <p>24 came in place. So, it applied only really for a</p> <p>25 few months at the end of that committee.</p>
<p style="text-align: right;">Page 103</p> <p>1 would -- if they asked me to do a cadaver course,</p> <p>2 say, one November, they would give me a contract</p> <p>3 that covered up to the next 12 months and usually</p> <p>4 the topic of that contract wouldn't come up until</p> <p>5 they had another product or cadaver lab they wanted</p> <p>6 me to attend.</p> <p>7 So, while the contracts overlapped or</p> <p>8 looked like it was continuous, it was really only</p> <p>9 event-specific.</p> <p>10 Q. I have looked at your consulting</p> <p>11 agreements. I'm sure you've looked at them too.</p> <p>12 They initiate -- for example, I'm looking at one</p> <p>13 February 1, 2011 and it says it would continue</p> <p>14 through January 31, 2012. So, your consulting</p> <p>15 agreements would be one year at a time, correct?</p> <p>16 A. Correct.</p> <p>17 Q. Was there any years -- from the time</p> <p>18 you -- rephrase.</p> <p>19 From the time you first started acting</p> <p>20 as a consultant, was there any year when you have</p> <p>21 not had a contract for that year?</p> <p>22 A. I don't know. There might have been a</p> <p>23 12 months in a row where I did no specific</p> <p>24 consulting. The contracts overlap that time</p> <p>25 period. And there was a time when I told them I</p>	<p style="text-align: right;">Page 105</p> <p>1 Q. A few months in 2012?</p> <p>2 A. Right. As far as I remember.</p> <p>3 (WHEREUPON, there was a short</p> <p>4 interruption.)</p> <p>5 BY MR. SLATER:</p> <p>6 Q. So, before 2012 the ACOG rules allowed</p> <p>7 you to be a paid consultant to Ethicon, correct?</p> <p>8 A. Correct.</p> <p>9 Q. For example, in 2011 I have your</p> <p>10 consulting agreement here, you were a paid</p> <p>11 consultant for that year, correct?</p> <p>12 A. I don't recall specifically, but it's</p> <p>13 very likely.</p> <p>14 Q. You testified before the FDA on</p> <p>15 September 8, 2011, correct?</p> <p>16 A. Yes.</p> <p>17 Q. Did you feel that you were required to</p> <p>18 testify truthfully when you testified to the FDA?</p> <p>19 A. Yes, I did.</p> <p>20 Q. You told the FDA that you had no</p> <p>21 conflicts of interest to disclose, correct?</p> <p>22 A. At that time I was not acting as a</p> <p>23 consultant to Ethicon, correct.</p> <p>24 Q. You were under contract with Ethicon at</p> <p>25 that time as a paid consultant, weren't you?</p>

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<p>1 MR. COMBS: And, Adam, I'm just going to 2 interject here. Tom Cartmell has fully deposed 3 Dr. Elser on this exact issue in the -- 4 MR. SLATER: Did he? 5 MR. COMBS: Yes. 6 MR. SLATER: Did he do a good job? 7 MR. COMBS: I thought so. 8 MR. SLATER: Okay. 9 THE WITNESS: He did. 10 MR. SLATER: I'll come back to this. 11 BY MR. SLATER: 12 Q. When you testified to the FDA regarding 13 pelvic mesh for treatment of prolapse and all the 14 things you told the FDA, were you telling the 15 truth? 16 A. Yes. 17 Q. Do you agree that the FDA's view of 18 whether or not adequate studies exist to prove the 19 safety and effectiveness of pelvic mesh kits for 20 prolapse like the Prolift is important? 21 MR. COMBS: Object to form. 22 BY THE WITNESS: 23 A. I'm sorry. Will you say that again. 24 Does the -- did I think that the FDA thinks there 25 needs to be more studies on safety of mesh kits?</p>	<p>1 to the 522 order? 2 A. No. 3 Q. Do you know why Ethicon removed the 4 Prolift from the market? 5 A. I don't know from Ethicon directly, no. 6 Q. Has anybody ever told you why the 7 Prolift was removed from the market? 8 A. I can tell you that I was told it was 9 because the cost of doing the studies was not 10 considered, wouldn't be a good balance with the 11 profit they could expect to make. But I don't know 12 who I heard that from or if it was a good source. 13 Q. Do you know whether Ethicon tried to 14 convince the FDA to accept studies that had already 15 been done instead of having to do the 522 studies? 16 A. No. I had heard from the FDA that they 17 were going to consider for all of the vaginal mesh 18 kits taking studies that had already been performed 19 into consideration at the end of a three-year 20 period. 21 MR. SLATER: Move to strike. 22 BY MR. SLATER: 23 Q. Do you know whether or not Ethicon tried 24 to convince the FDA to accept studies that had been 25 done on the Prolift instead of having to do the 522</p>
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<p>1 BY MR. SLATER: 2 Q. It's not what I asked you. 3 A. Okay. 4 Q. Do you agree that the FDA's viewpoint on 5 whether there's a need for more rigorous studies 6 regarding the safety and efficacy of mesh kits like 7 the Prolift is important? 8 A. Yes. 9 Q. Did you ever read the 522 orders that 10 were issued regarding the Prolift? 11 A. No. 12 Q. Actually, let me rephrase. 13 Did you ever read the 522 order that was 14 issued by the FDA with regard to the Prolift? 15 A. I might have read part of it, but I 16 don't remember if I read the whole thing. 17 Q. Do you recall anything about it? 18 A. I remember at least hearing about it. 19 Q. Well, here's my question. Do you recall 20 actually reading the 522 order regarding the 21 Prolift? 22 A. No. 23 Q. Do you know what it said? 24 A. No. 25 Q. Do you know what Ethicon did in response</p>	<p>1 studies? 2 MR. COMBS: Object to form. 3 BY THE WITNESS: 4 A. No. 5 BY MR. SLATER: 6 Q. So you wouldn't know what the FDA said 7 if that proposal was made by Ethicon, correct? 8 A. Correct. 9 Q. I want to ask you if the following 10 statement is true with regard to the Prolift: 11 Considering that native tissue repair is 12 an option for many women, it makes sense to use 13 vaginal mesh judiciously for vaginal prolapse 14 repairs. Is that a true statement regarding the 15 Prolift? 16 A. Yes. 17 Q. Mesh may be best for those considered 18 high risk in whom the benefit of mesh justifies the 19 risk of complications. Is that a true statement 20 for the Prolift? 21 A. Yes. 22 Q. For example, women with recurrent 23 prolapse, particularly in the anterior compartment 24 and those of medical co-morbidities that may 25 preclude more invasive and open or laparoscopic</p>

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<p style="text-align: right;">Page 110</p> <p>1 procedures, may be good candidates for vaginal 2 mesh. Is that a true statement regarding the 3 Prolift? 4 A. Yes. 5 Q. If you apply that criteria that we just 6 went through to Ms. Bellew -- rephrase. 7 So I want to now talk to you about 8 Ms. Bellew. She did not have recurrent prolapse 9 when Dr. DeHase operated on her in July 2009, 10 correct? 11 A. Correct. 12 Q. Ms. Bellew did not have medical 13 co-morbidities that precluded more invasive and 14 open or laparoscopic procedures, correct? 15 A. I disagree. She had emphysema. 16 Q. You think that she had -- she was 17 precluded from having that procedure? 18 A. It's a relative contraindication as is 19 the statement that Prolift is indicated for 20 recurrent prolapse. It was an example. It's not a 21 strict -- it's not a strict guideline. 22 Q. Here's my question: Is it your 23 testimony to a reasonable degree of medical 24 probability that Ms. Bellew was not a candidate for 25 an open or laparoscopic procedure to treat her</p>	<p style="text-align: right;">Page 112</p> <p>1 Q. Ms. Bellew was a good candidate for 2 native tissue repair, there were no 3 contraindications, correct? 4 MR. COMBS: Object to the form. Asked and 5 answered. 6 BY THE WITNESS: 7 A. Yes, but one of the considerations you 8 take is not just could the patient tolerate the 9 procedure, is she a candidate for it. But as you 10 read from the other statements is high risk for 11 recurrence. 12 Someone with -- who's a smoker with a 13 chronic cough and with emphysema/lung disease is 14 high risk for recurrent prolapse. So, a 15 consideration would be made. Are you at high risk 16 for failure after a native tissue repair, not can 17 you undergo the procedure. 18 MR. SLATER: Move to strike from "but" 19 forward. 20 BY MR. SLATER: 21 Q. Did you see a medical record where a 22 pulmonary specialist or an internal medicine 23 specialist with a focus on pulmonology diagnosed 24 Ms. Bellew with emphysema? 25 A. No.</p>
<p style="text-align: right;">Page 111</p> <p>1 prolapse? 2 A. I don't know the degree of her 3 emphysema. It's a clinical judgment on a 4 case-by-case basis per patient. One of the 5 decision-making factors whether you want to put 6 someone under general anesthetic with an 7 endotracheal tube for a two-and-a-half to four-hour 8 or more surgery for a laparoscopic robotic 9 sacrocolpopexy is the presence of lung disease or 10 other medical illnesses. So it's one of the 11 factors to consider. 12 I can't say it was precluded in her. 13 But it makes you think, oh, maybe a long abdominal 14 surgery in the Trendelenburg position with gas and 15 high pressure in your belly is not the best surgery 16 for you. 17 Q. You're not saying to a reasonable degree 18 of medical probability that Ms. Bellew was 19 contraindicated to having laparoscopic or open 20 surgery, correct? 21 MR. COMBS: Object to the form. 22 BY THE WITNESS: 23 A. Correct. I'm not saying she couldn't 24 have had it. She has risk factors for it. 25 BY MR. SLATER:</p>	<p style="text-align: right;">Page 113</p> <p>1 Q. No doctor actually has diagnosed 2 Ms. Bellew with emphysema, correct? 3 MR. COMBS: Object to form. 4 BY THE WITNESS: 5 A. Are you talking about before or after 6 the Prolift surgery? 7 BY MR. SLATER: 8 Q. I'm asking you at any point. There is 9 no doctor who has actually evaluated Ms. Bellew in 10 order to reach a diagnosis as to whether or not she 11 has emphysema. That has not occurred, correct? 12 A. I have seen emphysema in the medical 13 records and she has been placed on oxygen at some 14 point. 15 Q. The fact that some doctor may have used 16 the word emphysema doesn't mean Ms. Bellew has a 17 diagnosis of emphysema, correct? 18 MR. COMBS: Object to the form. 19 BY THE WITNESS: 20 A. Yes, but it's most common that a doctor 21 uses a term like emphysema when it's a diagnosis 22 the patient has. 23 MR. SLATER: Move to strike from "yes" 24 forward. 25 BY MR. SLATER:</p>

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<p style="text-align: right;">Page 114</p> <p>1 Q. You're not offering the opinion to a 2 reasonable degree of medical probability that 3 Ms. Bellew had emphysema, correct? 4 A. I would like to defer that to look 5 through the records where we saw the diagnosis of 6 emphysema. I don't know if she had full-blown 7 emphysema diagnosed before the Prolift, but she is 8 a smoker. 9 Q. All smokers don't have emphysema, right? 10 A. No, but -- but she -- it's in her 11 records now that emphysema. So, we can -- 12 Q. Doctor, here's my question. 13 A. Yeah. 14 Q. I read your report. 15 A. Yes. 16 Q. I'm deposing you now. I have limited 17 time. 18 You have not formed the opinion to a 19 reasonable degree of medical probability that 20 Ms. Bellew has emphysema, correct? 21 A. I believe she has emphysema. I would 22 like to look at the records with you where I saw 23 that diagnosis. 24 Q. Let me ask you this question. 25 A. I have not read the pulmonologist</p>	<p style="text-align: right;">Page 116</p> <p>1 placed on oxygen because she has lung disease? 2 Q. Well, I don't know why she was placed on 3 oxygen or what the thought process was or how the 4 word lung disease is used, so I'm not going to 5 agree to that. 6 Let me ask you this: You're not forming 7 the opinion to a reasonable degree of medical 8 probability that Ms. Bellew's history of smoking 9 contributed or caused her Prolift-related 10 complications, correct? 11 MR. COMBS: Object to the form. 12 BY THE WITNESS: 13 A. No. Smoking is a risk factor for 14 exposure, which we haven't seen. But we were 15 talking about risk factors for recurrence why a 16 Prolift might be chosen as a surgery. 17 MR. SLATER: Move to strike after "no." 18 BY MR. SLATER: 19 Q. Ms. Bellew's neck condition did not 20 cause or contribute to her Prolift complications, 21 correct? 22 A. No, not directly. 23 Q. Ms. Bellew's back condition did not 24 cause Ms. Bellew's Prolift complications, correct? 25 A. I don't know.</p>
<p style="text-align: right;">Page 115</p> <p>1 report. 2 Q. Let me ask you this. 3 A. Yeah. 4 Q. What test or examination by a doctor for 5 the purpose of diagnosing emphysema are you relying 6 on? I never saw one. I want to know is there 7 something that happened that I'm missing? 8 A. No, I have not seen a test performed, 9 but patients aren't placed on home oxygen if they 10 don't have lung disease. 11 Q. There's patients that use oxygen who do 12 not have clinical emphysema, correct? 13 A. Correct. 14 Q. As you sit here now, because, again, I 15 have limited time, as you sit here now, there is no 16 clinical diagnosis by somebody who actually 17 specializes with regard to lung diseases of 18 emphysema in her records, correct? 19 A. No, I can't say that. I can look 20 through the records to find which page the word 21 emphysema is on so we can decide if it was a valid 22 diagnosis or not. 23 Q. We can both agree the word emphysema 24 appears in her medical records, right? 25 A. Yes, and can we agree that she was</p>	<p style="text-align: right;">Page 117</p> <p>1 Q. You're not forming that opinion as you 2 sit here now, right? 3 A. I think it may have contributed. I 4 don't know. 5 Q. But you're not forming that opinion to a 6 reasonable degree of medical probability. You're 7 saying maybe but I can't say it to a reasonable 8 degree of medical probability, correct? 9 A. Correct. I am not saying it caused her 10 Prolift complications. I am saying it could be a 11 contributing factor to her pelvic pain. 12 Q. Could be, could not be. You're not 13 saying more likely than not, right? 14 A. Correct. 15 Q. With regard to her neck pain, again, 16 you're not saying to a reasonable degree of medical 17 probability it was the cause of the complications 18 attributed to her Prolift, correct? 19 A. No, but when a patient has chronic 20 myofascial problems in another part of the body and 21 lower back pain and neck pain, shoulder pain, she 22 may also have fibromyalgia which would be a 23 contributing factor. So, I wish it had been 24 explored more in this patient, but I can't say for 25 sure she has it.</p>

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<p>1 Q. Let me ask you this. With regard to the</p> <p>2 neck pathology that was operated on by a surgeon,</p> <p>3 that did not cause or contribute to the Prolift</p> <p>4 complications, correct?</p> <p>5 A. No.</p> <p>6 MR. COMBS: Object to the form.</p> <p>7 BY THE WITNESS:</p> <p>8 A. Unless that's what's triggered her</p> <p>9 fibromyalgia. But other than that, no.</p> <p>10 BY MR. SLATER:</p> <p>11 Q. Ms. Bellew's vascular condition did not</p> <p>12 cause or contribute to her Prolift complications,</p> <p>13 correct?</p> <p>14 A. No.</p> <p>15 Q. Meaning I'm correct?</p> <p>16 A. No, you're correct.</p> <p>17 Q. I just got to watch double negatives.</p> <p>18 Is it your opinion that Ms. Bellew had</p> <p>19 chronic fibromyalgia before the Prolift was put in</p> <p>20 her body in other parts of her body away from the</p> <p>21 pelvis?</p> <p>22 A. I think she may have. I don't see a</p> <p>23 diagnosis of fibromyalgia being made. But I -- I</p> <p>24 would be suspicious that she has it.</p> <p>25 Q. Have you formed an opinion to a</p>	<p>1 IFU?</p> <p>2 A. No, because fibromyalgia was discussed</p> <p>3 in the surgeons monograph.</p> <p>4 Q. Do all doctors see the surgeons</p> <p>5 monograph before they use the Prolift?</p> <p>6 A. No, but I think it's available if</p> <p>7 they -- if they want to see it.</p> <p>8 MR. SLATER: Move to strike after "no."</p> <p>9 BY MR. SLATER:</p> <p>10 Q. Do you understand the purpose of the IFU</p> <p>11 under federal regulations?</p> <p>12 A. No. I understand how it's used in -- in</p> <p>13 clinical practice.</p> <p>14 Q. But you don't know the purpose of the</p> <p>15 IFU in terms of why it's put into the box with the</p> <p>16 product?</p> <p>17 A. Correct.</p> <p>18 Q. When you told the FDA that rigorous</p> <p>19 effective trials of native tissue repair comparing</p> <p>20 to vaginal mesh would be required, did you mean</p> <p>21 what you said?</p> <p>22 MR. COMBS: Object to the form.</p> <p>23 BY THE WITNESS:</p> <p>24 A. I was presenting the ACOG opinion from</p> <p>25 the committee. This was not my personal -- these</p>
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<p>1 reasonable degree of medical probability that</p> <p>2 Ms. Bellew had fibromyalgia somewhere in her body</p> <p>3 other than the pelvis before the Prolift was</p> <p>4 implanted or are you just saying it's possible?</p> <p>5 A. I'm saying it's possible.</p> <p>6 Q. The -- rephrase.</p> <p>7 Did you see that Ms. Bellew had a</p> <p>8 mystery of migraine headaches?</p> <p>9 A. Yes.</p> <p>10 Q. Do you know whether Ethicon internally</p> <p>11 believed that a woman with a chronic pain</p> <p>12 condition, even migraines, would have an increased</p> <p>13 risk for pain after Prolift surgery?</p> <p>14 MR. COMBS: Object to the form.</p> <p>15 BY MR. SLATER:</p> <p>16 Q. Do you know what Ethicon thought about</p> <p>17 that?</p> <p>18 A. I'd like to look at the monograph.</p> <p>19 There might have been something about migraines in</p> <p>20 the monograph, but I don't recall specifically.</p> <p>21 Q. If Ethicon Medical Affairs believed that</p> <p>22 women with a chronic pain condition like migraines</p> <p>23 or even fibromyalgia or anything like that could be</p> <p>24 at increased risk to develop pain after Prolift</p> <p>25 surgery, should that have been warned about in the</p>	<p>1 are not my personal statements.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. So, when you testified to the FDA to</p> <p>4 that effect, you were telling the FDA this is what</p> <p>5 ACOG thinks but you at the time did not believe</p> <p>6 that to be true. Do I understand you correctly?</p> <p>7 A. Yes, I disagreed with that one</p> <p>8 statement.</p> <p>9 Q. When you told the FDA eventually the</p> <p>10 best method to compare native tissue repair --</p> <p>11 rephrase.</p> <p>12 When you told the FDA that eventually</p> <p>13 the best method to compare native tissue repairs</p> <p>14 and vaginal mesh for prolapse is a randomized</p> <p>15 controlled trial with adequate length of follow-up</p> <p>16 and blinded assessment of outcome by independent</p> <p>17 observers, was that ACOG's position?</p> <p>18 A. Yes.</p> <p>19 Q. Did you agree with that position?</p> <p>20 A. I think we talked about before the break</p> <p>21 that I would not necessarily want to compare</p> <p>22 patients to randomize them to native tissue or mesh</p> <p>23 because it's not necessarily the same group of</p> <p>24 patients in my book. I think clinical judgment</p> <p>25 plays a role.</p>

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<p style="text-align: right;">Page 122</p> <p>1 So, I personally disagreed with</p> <p>2 randomizing native tissue to mesh, but I agree with</p> <p>3 blinded assessment of the outcomes and long-term</p> <p>4 follow-up.</p> <p>5 Q. And you don't believe that randomizing</p> <p>6 patients to native tissue repair and Prolift, for</p> <p>7 example, that such a study would be useful?</p> <p>8 A. It would be interesting but it would</p> <p>9 have its limitations.</p> <p>10 Q. So, to the extent that any such studies</p> <p>11 appear on your list, those would be studies you'd</p> <p>12 say are interesting but not something you'd rely on</p> <p>13 for your opinions. Do I understand correctly?</p> <p>14 A. No. I think you originally asked if</p> <p>15 they were useful. Yes, they are useful. I don't</p> <p>16 think it's the end-all -- necessarily going to be</p> <p>17 the end-all-be-all study depending on the patient</p> <p>18 population studied.</p> <p>19 Q. Do you agree with me that success rates</p> <p>20 based solely on anatomic outcomes are inadequate?</p> <p>21 A. Yes.</p> <p>22 Q. Do you think the Altman study published</p> <p>23 in the New England Journal of Medicine in 2011 is a</p> <p>24 reliable study?</p> <p>25 A. Yes, I do.</p>	<p style="text-align: right;">Page 124</p> <p>1 would not be reliable?</p> <p>2 MR. COMBS: Object to the form.</p> <p>3 BY THE WITNESS:</p> <p>4 A. No, I think it would depend if the</p> <p>5 errors in measurement were consistent.</p> <p>6 BY MR. SLATER:</p> <p>7 Q. Well, if there is an error in a POP-Q</p> <p>8 measurement and the number that is put down is not</p> <p>9 impossible, you can't always even tell that an</p> <p>10 error has been made, correct?</p> <p>11 A. That sounds correct.</p> <p>12 Q. So, therefore, if impossible</p> <p>13 measurements are being found and it's not just one</p> <p>14 or two isolated incidents, you have to question</p> <p>15 whether the balance of the measurements are</p> <p>16 accurate as well, right?</p> <p>17 A. I think this is really theoretical. So,</p> <p>18 if it's a consistent error made and it's applied to</p> <p>19 all the measurements, whether it's from one site or</p> <p>20 one documenter or on both sides of the RCT, then as</p> <p>21 long as it's a consistent error, it shouldn't</p> <p>22 affect the overall outcome conclusion.</p> <p>23 Q. When you say it's theoretical, you're</p> <p>24 saying that because you don't know that that</p> <p>25 happens in any particular study, right?</p>
<p style="text-align: right;">Page 123</p> <p>1 Q. Did you ever -- well, you didn't --</p> <p>2 rephrase.</p> <p>3 You never read Dr. Drazen's deposition,</p> <p>4 the editor of the New England Journal of Medicine,</p> <p>5 you never read that, right?</p> <p>6 A. No.</p> <p>7 Q. And you haven't seen any documents</p> <p>8 regarding Ethicon's input into that study?</p> <p>9 A. No.</p> <p>10 Q. If there is a systemic problem with the</p> <p>11 POP-Q measurements in a study that is measuring</p> <p>12 anatomic recurrences, you can't rely on the</p> <p>13 recurrence rates, correct?</p> <p>14 MR. COMBS: Object to the form.</p> <p>15 BY THE WITNESS:</p> <p>16 A. It would depend on what kind of</p> <p>17 systematic problem there was.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. How about if the people reviewing the</p> <p>20 data were finding impossible POP-Q measurements and</p> <p>21 had no way of knowing whether the possible</p> <p>22 measurements were actually accurate or not because</p> <p>23 of questions of whether or not those doing the</p> <p>24 measurements really understood the system. In that</p> <p>25 scenario would you agree that the recurrence rates</p>	<p style="text-align: right;">Page 125</p> <p>1 A. Right.</p> <p>2 Q. If there were errors in the POP-Q</p> <p>3 measurements, you would need to know more detail</p> <p>4 about the extent and have the opportunity to</p> <p>5 evaluate those measurements yourself before you</p> <p>6 could say whether or not you would trust the</p> <p>7 recurrence rates, correct?</p> <p>8 A. Well, I might consult a statistician</p> <p>9 but, for example, if you're going to say a minus 2</p> <p>10 measurement is always perfect and the person made a</p> <p>11 mistake, every time it was minus 2, they said zero,</p> <p>12 it's going to affect the overall end measurement</p> <p>13 but may not -- may not change our conclusions if</p> <p>14 the mistake is made consistently.</p> <p>15 Q. Yeah, I'm not looking -- with all due</p> <p>16 respect, Doctor, I am not asking for reasons why it</p> <p>17 may be that you could ultimately decide that the</p> <p>18 numbers are okay.</p> <p>19 This is my question: If it was brought</p> <p>20 to your attention that with regard to a particular</p> <p>21 study there were questions about the POP-Q</p> <p>22 measurements and documented errors were shown, you</p> <p>23 would want to see the measurements, you'd want to</p> <p>24 see the pattern of errors and then based on that</p> <p>25 information you would then want to form an opinion</p>

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<p style="text-align: right;">Page 126</p> <p>1 of whether or not you still find the recurrence</p> <p>2 rates to be reliable. Is that a true statement?</p> <p>3 MR. COMBS: Object to the form.</p> <p>4 BY THE WITNESS:</p> <p>5 A. No. I would defer it to the editors who</p> <p>6 have statisticians at their disposal to conclude</p> <p>7 whether or not the document has -- is valid to</p> <p>8 publish in their journal as well as the peer</p> <p>9 reviewers.</p> <p>10 BY MR. SLATER:</p> <p>11 Q. So you wouldn't want to look at the data</p> <p>12 yourself to draw your own independent opinion?</p> <p>13 A. I don't think so.</p> <p>14 Q. Do you consider yourself to be an expert</p> <p>15 with regard to clinical study design?</p> <p>16 A. I've been involved in clinical study</p> <p>17 design, yes, but not -- I'm not an expert as far as</p> <p>18 statistics.</p> <p>19 Q. Let me ask you something about the IFU.</p> <p>20 Rephrase.</p> <p>21 Let me ask you something about the</p> <p>22 Prolift IFU. What specific information would you</p> <p>23 say actually needed to be in there to warn doctors</p> <p>24 of risks and complications? What did it need to</p> <p>25 actually say?</p>	<p style="text-align: right;">Page 128</p> <p>1 them and perhaps to take care of them</p> <p>2 postoperatively if there is something unusual.</p> <p>3 Q. So, coming back to my question.</p> <p>4 Do I understand you correctly that from</p> <p>5 your perspective the Prolift IFU did not need to</p> <p>6 list the potential risks and complications from</p> <p>7 using the Prolift? Do I understand that correctly?</p> <p>8 MR. COMBS: Object to the form.</p> <p>9 BY THE WITNESS:</p> <p>10 A. Again, I don't think you need to list</p> <p>11 every -- every risk and every complication because</p> <p>12 most of those should be known.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. Any that you think needed to be listed?</p> <p>15 A. Outside of what is listed or just</p> <p>16 anything in general?</p> <p>17 Q. I want to ask -- I'm asking you if</p> <p>18 you're going to -- if you were writing the Prolift</p> <p>19 IFU, are there any risks and complications that you</p> <p>20 think would need to be listed in the IFU?</p> <p>21 A. I would list the risks of placing the</p> <p>22 trocars, how you place them, over your finger, with</p> <p>23 the proper place to position your incision so that</p> <p>24 you can pass the trocars through the obturator</p> <p>25 space in the safest manner possible.</p>
<p style="text-align: right;">Page 127</p> <p>1 A. Well, since the only thing unique about</p> <p>2 Prolift as compared to other vaginal mesh repairs</p> <p>3 or using mesh abdominally is really the introducers</p> <p>4 and the arms, I'd say then it should have</p> <p>5 information about the trocar arms, how they're</p> <p>6 placed and the mesh arms, how they are adjusted.</p> <p>7 Q. In terms of risks and complications, do</p> <p>8 I understand you correctly that there really</p> <p>9 doesn't need to be any information in the IFU</p> <p>10 regarding risks and complications from the Prolift</p> <p>11 because you would assume doctors would just know</p> <p>12 those on their own anyway?</p> <p>13 MR. COMBS: Object to the form.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Well, the -- since the Prolift -- it was</p> <p>16 recommended to be used by surgeons who are familiar</p> <p>17 with pelvic reconstructive surgery and have</p> <p>18 experience with implanting synthetic mesh, I expect</p> <p>19 risks specific to pelvic organ prolapse surgery or</p> <p>20 placement of mesh to be known to people adopting</p> <p>21 Prolift.</p> <p>22 So, the unique things that I would want</p> <p>23 to see in the IFU before adopting are what's unique</p> <p>24 about the trocar delivery system and what's unique</p> <p>25 about the mesh arms, either to lay them, to adjust</p>	<p style="text-align: right;">Page 129</p> <p>1 Q. So, if I understand, you're saying the</p> <p>2 IFU from your perspective would need to explain how</p> <p>3 to use the trocars but you wouldn't need to list</p> <p>4 the risks or complications that could occur from</p> <p>5 Prolift surgery. Do I understand that?</p> <p>6 MR. COMBS: Object to the form.</p> <p>7 BY THE WITNESS:</p> <p>8 A. Well, what clinicians use an IFU for</p> <p>9 primarily is to understand the procedural steps if</p> <p>10 it's an unfamiliar procedure.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. So I'm understanding you correctly, from</p> <p>13 your perspective, the Prolift IFU did not need to</p> <p>14 list any particular risks or complications,</p> <p>15 correct?</p> <p>16 A. Unless they were unique to this device.</p> <p>17 Q. Well, are there any that you would say</p> <p>18 are unique and needed to be included?</p> <p>19 A. What's unique to this?</p> <p>20 Q. That's not -- Dr. Elser, let me ask you</p> <p>21 again.</p> <p>22 You said unless they're unique and then</p> <p>23 I asked you what do you think needed to be included</p> <p>24 and then you asked me as if I was asking a new</p> <p>25 question. So, with all due respect, let's not go</p>

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<p style="text-align: right;">Page 130</p> <p>1 in circles. Okay?</p> <p>2 A. Okay.</p> <p>3 Q. So let's do this. I'm going to come</p> <p>4 back to my question.</p> <p>5 Are there any specific risks or</p> <p>6 complications that you think needed to be in the</p> <p>7 Prolift IFU?</p> <p>8 A. You could talk about the risk if you</p> <p>9 make the arms too tight, if improper tensioning is</p> <p>10 used. These are things that are unique to the</p> <p>11 Prolift that would be helpful to a surgeon.</p> <p>12 Q. And what are those risks?</p> <p>13 A. Well, undue tension is placed on the</p> <p>14 mesh arms, I expect a higher risk of pain</p> <p>15 afterwards or fibrosis because of tension.</p> <p>16 The thing that was unique to vaginal</p> <p>17 mesh kits outside of the obturator trocars is the</p> <p>18 full thickness dissection, which is talked about in</p> <p>19 the surgeons monograph and is talked about in the</p> <p>20 procedural videos. But placing the mesh in the</p> <p>21 proper space in the pelvis was new to using vaginal</p> <p>22 mesh that was not necessarily always done with --</p> <p>23 with mesh that was placed without a kit before</p> <p>24 that.</p> <p>25 MR. SLATER: Move to strike.</p>	<p style="text-align: right;">Page 132</p> <p>1 everything else is known to vaginal surgeons. If</p> <p>2 you are asking me what needs to be listed because</p> <p>3 of government regulations, I can't answer it.</p> <p>4 Q. Do you know whether somebody in Ethicon</p> <p>5 Regulatory Affairs who was involved in drafting the</p> <p>6 Prolift IFU has testified that it is not legitimate</p> <p>7 to fail to warn of something based on an assumption</p> <p>8 that doctors would know it?</p> <p>9 MR. COMBS: Object to form.</p> <p>10 BY MR. SLATER:</p> <p>11 Q. Are you aware of that testimony?</p> <p>12 MR. COMBS: Object to form.</p> <p>13 BY THE WITNESS:</p> <p>14 A. No.</p> <p>15 BY MR. SLATER:</p> <p>16 Q. You noted in your report that Ms. Bellew</p> <p>17 used pain medication for her orthopedic condition,</p> <p>18 correct?</p> <p>19 A. Yes.</p> <p>20 Q. That's of no significance to you with</p> <p>21 regard to the Prolift injuries that are at issue in</p> <p>22 this case, correct?</p> <p>23 MR. COMBS: Object to form.</p> <p>24 BY THE WITNESS:</p> <p>25 A. I mention it because my concerns are</p>
<p style="text-align: right;">Page 131</p> <p>1 BY MR. SLATER:</p> <p>2 Q. Doctor, I'm going to try this again.</p> <p>3 A. I'm sorry. I guess I'm not</p> <p>4 understanding what you want.</p> <p>5 Q. I don't know. You're talking about the</p> <p>6 monograph and I'm asking you a narrow question</p> <p>7 about what needs to be in the IFU. So, I'm not</p> <p>8 really sure why we're talking about other</p> <p>9 documents. Let me try this again with you.</p> <p>10 My question is what specific risks, not</p> <p>11 what needs to be explained about how to do the</p> <p>12 procedure. Okay. I'm not asking about what</p> <p>13 procedural information needs to be given about how</p> <p>14 to do the procedure. Okay?</p> <p>15 A. Okay.</p> <p>16 Q. I'm not asking about that section of</p> <p>17 describing the operation.</p> <p>18 So now I'm asking you in the sections</p> <p>19 titled "Warnings" and "Adverse Events," what risks</p> <p>20 and complications need to be in the Prolift IFU in</p> <p>21 those sections. You've told me if the arm is too</p> <p>22 tight that can lead to too much tension and a</p> <p>23 higher risk of pain. Any other risks that need to</p> <p>24 be included in the IFU? I just want a list.</p> <p>25 A. To be helpful to clinicians, no, because</p>	<p style="text-align: right;">Page 133</p> <p>1 somebody who has chronic pain in one area is more</p> <p>2 likely to develop chronic pain in another part of</p> <p>3 the body and chronic narcotics users are often</p> <p>4 constipated and that may be underaddressed in the</p> <p>5 Prolift patient. So, chronic straining, well, it's</p> <p>6 a risk factor for recurrent prolapse and a risk</p> <p>7 factor for pelvic floor myofascial pain.</p> <p>8 BY MR. SLATER:</p> <p>9 Q. From your perspective, if somebody has</p> <p>10 chronic pain anywhere in their body before a</p> <p>11 Prolift, they'd be at a higher risk to develop</p> <p>12 chronic pain from the Prolift afterwards. Do I</p> <p>13 understand you correctly?</p> <p>14 A. Yes.</p> <p>15 Q. Is it true that you stopped using the</p> <p>16 Prolift because you were concerned about patients</p> <p>17 who were developing pain two to three years</p> <p>18 postoperatively?</p> <p>19 A. I don't recall that. I had some</p> <p>20 patients with late onset of pain. But I had -- I</p> <p>21 had used the Prolift -- planned to use it right up</p> <p>22 until the time that it was stopped being marketed.</p> <p>23 Q. Do you remember someone named Bart</p> <p>24 Patterson?</p> <p>25 A. Yes, I do.</p>

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<p>1 Q. You worked closely with Bart Patterson</p> <p>2 from Ethicon professional education, correct?</p> <p>3 A. Yes.</p> <p>4 Q. And from time to time you would tell him</p> <p>5 about your experience with various products sold by</p> <p>6 Ethicon, right?</p> <p>7 A. Right.</p> <p>8 Q. And if Bart Patterson documented that</p> <p>9 you had experienced some two-to-three-year</p> <p>10 postoperative pain with some of your Prolift</p> <p>11 patients so you were currently holding off on the</p> <p>12 procedure for some of your patients, would that be</p> <p>13 accurate?</p> <p>14 A. That sounds about right.</p> <p>15 Q. Which types of patients did you start to</p> <p>16 hold off on using the Prolift with once you started</p> <p>17 seeing two to three years postoperative pain</p> <p>18 developing?</p> <p>19 MR. COMBS: Object to form.</p> <p>20 BY THE WITNESS:</p> <p>21 A. I can't say.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. You do agree that when you started</p> <p>24 seeing patients coming to you two to three years</p> <p>25 after their Prolifts were placed suffering from</p>	<p>1 was usually at the mesh arm with some contraction</p> <p>2 at the mesh arm.</p> <p>3 Q. In fact, Ms. Bellew about two years</p> <p>4 after her Prolift surgery was found to have</p> <p>5 contraction, banding, hardening of the mesh arm</p> <p>6 leading to pain and dyspareunia which led to three</p> <p>7 excision surgeries, correct?</p> <p>8 MR. COMBS: Object to the form.</p> <p>9 BY THE WITNESS:</p> <p>10 A. Yes, she had pain at the mesh arm with</p> <p>11 fibrosis and contraction there.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. I saw some places in your report where</p> <p>14 you talked about the risks that are unique to the</p> <p>15 Prolift and you talked about erosion and exposure,</p> <p>16 right?</p> <p>17 A. Right.</p> <p>18 Q. Another risk that is unique to the</p> <p>19 Prolift as compared to native tissue is mesh</p> <p>20 contraction, mesh banding, mesh hardening and all</p> <p>21 of the things that can flow from that, correct?</p> <p>22 A. Contraction around the mesh, right. But</p> <p>23 we can see fibrotic scar banding with native tissue</p> <p>24 repairs.</p> <p>25 Q. If you see -- rephrase from "but"</p>
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<p>1 chronic pelvic pain, you started to exclude some of</p> <p>2 your patients as candidates for Prolift, correct?</p> <p>3 A. I do remember talking to Bart about</p> <p>4 holding off a while while I saw how patients -- see</p> <p>5 how patients responded, how they did with</p> <p>6 treatment.</p> <p>7 Q. And that's because you started to</p> <p>8 hold -- rephrase.</p> <p>9 And that's because you started to</p> <p>10 exclude some of your patients from the Prolift once</p> <p>11 you started to see these postoperative chronic pain</p> <p>12 two to three years after the surgery, right?</p> <p>13 A. Yeah, I don't remember the specific</p> <p>14 communications and I don't remember which patients</p> <p>15 I would have excluded. So, I can't tell you</p> <p>16 details.</p> <p>17 Q. You were excluding some of your patients</p> <p>18 because you were concerned about long-term chronic</p> <p>19 pelvic pain developing after Prolift, correct?</p> <p>20 A. I was concerned.</p> <p>21 Q. One of your concerns was that some of</p> <p>22 those patients were developing contractions and</p> <p>23 tension banding of the mesh and dyspareunia as a</p> <p>24 result, correct?</p> <p>25 A. If they came back with pain later, it</p>	<p>1 forward.</p> <p>2 When there is fibrosis and fibrotic</p> <p>3 bridging and contraction of the mesh, that does not</p> <p>4 soften over time. That remains hard and continues</p> <p>5 to progress in many women. Correct?</p> <p>6 MR. COMBS: Object to form.</p> <p>7 BY THE WITNESS:</p> <p>8 A. No.</p> <p>9 BY MR. SLATER:</p> <p>10 Q. Are you familiar with what Ethicon</p> <p>11 thinks about that question, the people in that</p> <p>12 company that have actually studied this subject?</p> <p>13 A. They may have studied a lot of things in</p> <p>14 the lab. I can explain how I feel it affects our</p> <p>15 patients.</p> <p>16 Q. Let me ask you this: Are you aware of</p> <p>17 whether Ethicon is constantly in communication with</p> <p>18 doctors and surgeons not only in the United States</p> <p>19 but around the world about their products including</p> <p>20 Prolift?</p> <p>21 A. I'm not aware to the extent, no. I</p> <p>22 imagine they are in contact with physicians who use</p> <p>23 the products.</p> <p>24 Q. You made no effort to learn what Ethicon</p> <p>25 Medical Affairs knew from its outreach to doctors</p>

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<p>1 around the world about the Prolift and the extent 2 of complications, correct? 3 A. Correct. 4 Q. When a woman has scarring after a native 5 tissue repair, that will usually soften and resolve 6 over the course of time, correct? 7 A. Not necessarily. 8 Q. I didn't say in all cases, but for the 9 most part it will, right? 10 A. It depends on what it -- when it's 11 presenting. 12 Q. The majority of the time that a woman 13 has some scarring and discomfort from that scarring 14 after native tissue repair, that will resolve over 15 time as the scar softens, correct? 16 A. No. Again, it depends when it presents. 17 If it's for six-week postoperative check and she 18 has pain and scarring, yes, that's likely going to 19 soften up with time. If she comes back a year or 20 more after her surgery with a scar band that's a 21 very taut, contracted scar band, whether it's 22 around a suture or not, that may not soften up. 23 Q. That would be very rare after a native 24 tissue surgery, right? 25 A. I don't think it's very rare.</p>	<p>1 A. Correct. 2 Q. And you believe that it would be 3 appropriate for her to have physical therapy for 4 the pelvic floor and a dilator and other treatment 5 to try to resolve that or to make that better, 6 correct? 7 A. I think physical therapy, pelvic floor 8 physical therapy, yes, absolutely. Possibly she'd 9 benefit from a dilator. 10 Q. Pelvic floor physical therapy is 11 invasive, correct? 12 A. Usually. 13 Q. Pelvic floor physical therapy is not 14 successful in all women in completely resolving 15 their myofascial pain in their pelvic floor. In 16 fact, usually with somebody who has chronic pelvic 17 floor myalgia, at best it will just help to reduce 18 the pain, correct? 19 A. I don't know if I agree. It depends on 20 the quality of the physical therapist and the 21 patient's willingness to perform her exercises on a 22 regular basis. But we see for the majority great 23 success with pelvic floor physical therapy. 24 Q. Is there any study you can point to that 25 actually studied the question of the success of</p>
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<p>1 Q. Do you have any statistics or data you 2 can point to on that? 3 A. We can talk about risk of -- new onset 4 of pain after native tissue repairs. 5 Q. I'm talking about the specific issue -- 6 A. Specifically scar banding? 7 Q. I'm talking about somebody having what 8 you called a scar band after native tissue repair 9 more than a year after the surgery. That would be 10 rare, correct? 11 A. It's -- most patients don't get it. I 12 wouldn't call it rare. We certainly see it on a 13 regular basis in our urogynecology practice. 14 Q. If Ms. Bellew had had an alternative 15 procedure like native tissue repair with suture, 16 you can't say that she would have suffered any 17 particular complications from that. That would be 18 speculative. Correct? 19 MR. COMBS: Object to form. 20 BY THE WITNESS: 21 A. Yes. 22 BY MR. SLATER: 23 Q. It's my understanding that you believe 24 Ms. Bellew has myofascial pain from pelvic floor 25 myalgia, correct?</p>	<p>1 pelvic floor physical therapy in a woman with 2 chronic pelvic floor myalgia? 3 A. No, there is not. There is a paucity of 4 that data in our literature. So I'm relying on 5 clinical experience. 6 Q. Whether or not Ms. Bellew used estrogen 7 in her vagina had nothing to do with her developing 8 contractions and fibrosis of the mesh itself, 9 correct? 10 A. No, not necessarily. Estrogen does 11 promote healing and a thin post-menopausal vaginal 12 epithelium is more likely to sclerose and fibrose. 13 Q. Well, the sclerosis and fibrosis of the 14 mesh occurred behind the vaginal wall, not in the 15 vaginal wall, correct? 16 MR. COMBS: Object to form. 17 BY THE WITNESS: 18 A. I don't think so. I think in her case, 19 because it's being described by Dr. DeHasse as a 20 split thickness dissection, that it was placed in 21 the wall of the vagina, not behind it. 22 BY MR. SLATER: 23 Q. You believe what was placed in the wall 24 of the vagina? 25 A. The mesh.</p>

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<p>1 Q. You don't believe there was a full 2 thickness dissection? 3 A. I don't. 4 Q. Is that opinion in your report? 5 A. I believe it is. 6 Q. From what you read in the procedure and 7 Dr. DeHasse's deposition, did she know about the 8 need for a full thickness dissection after taking 9 Ethicon's professional education course? 10 A. I don't know what she knew about, but 11 she testified in her deposition that she performed 12 a split thickness dissection. 13 Q. Did she say that for the entire Prolift 14 or was she talking about the hysterectomy? 15 A. It would be for the Prolift portion. 16 Q. The full thickness dissection is 17 performed in order to reduce the risk of mesh 18 exposure into the vagina, correct? 19 A. Yes, but I believe it also helps prevent 20 the scarring and fibrosis. If you have got a mesh 21 embedded in the skin, it's more likely to be stuck 22 in its position. 23 MR. SLATER: Move to strike after "yes." 24 BY MR. SLATER: 25 Q. Is there any document whatsoever that</p>	<p>1 dissections, correct? 2 A. They were trained to do split thickness 3 native tissue repairs. 4 Q. Right. And to a large -- rephrase. 5 And it's fair to say that the full 6 thickness dissection is counterintuitive to many 7 physicians, correct? 8 MR. COMBS: Object to the form. 9 BY THE WITNESS: 10 A. It may be counterintuitive, but then 11 mesh may also be counterintuitive. 12 BY MR. SLATER: 13 Q. Is the answer to my question yes, that 14 the full thickness dissection is counterintuitive 15 to many physicians? 16 MR. COMBS: Object to form. 17 BY THE WITNESS: 18 A. Yes. For a general Ob-Gyn who trained 19 in a program where only native tissue repairs were 20 performed, they likely only learned split thickness 21 repairs, which applies only to native tissue 22 repair. 23 BY MR. SLATER: 24 Q. You cannot say whether or not -- 25 rephrase.</p>
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<p>1 you can point to anywhere in the world that says 2 that the reason for the full thickness dissection 3 is to in any way impact on the risk of having 4 contraction or fibrotic bridging on the mesh? 5 A. No, this is my clinical experience. 6 Q. And are there patients you've seen where 7 you believe there was not a full thickness 8 dissection and they had mesh contraction that you 9 attributed to the type of dissection, that's 10 something you're saying you've seen in your 11 experience? 12 A. Yes. 13 Q. How many times? 14 A. Several. When we first used self-cut 15 mesh to put in the vagina, we were not doing full 16 thickness dissection. It was not until more 17 experience and experiencing the fibrosis and the 18 extrusions at multiple sites from trying to put 19 mesh in a split thickness dissection that we 20 learned a better position was in the true 21 paravesical space behind the full thickness 22 epithelium. 23 Q. The full thickness dissection is 24 contrary to the training and education of many 25 physicians who were trained to do split thickness</p>	<p>1 You would agree with me it's more likely 2 than not that Ms. Bellew still would have had 3 contractions, fibrosis and hardening of the mesh 4 regardless of which type of dissection was 5 performed here, correct? 6 A. No, I can't say that. 7 Q. Do you have an opinion one way or the 8 other or you're just saying it's possible it could 9 have happened, possible it wouldn't have; 10 speculative but it's possible? 11 MR. COMBS: Object to form. 12 BY THE WITNESS: 13 A. I think it's very likely that if you put 14 the mesh in a split thickness in the wall of the 15 epithelium, you're causing fibrosis, more likely to 16 cause scarring. 17 BY MR. SLATER: 18 Q. It would be speculative what -- to say 19 what would have happened if a full thickness 20 dissection was done as you've said? 21 MR. COMBS: Object. 22 BY MR. SLATER: 23 Q. Is that fair? 24 MR. COMBS: Object to form. 25 BY THE WITNESS:</p>

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<p style="text-align: right;">Page 146</p> <p>1 A. Yes.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. Yes?</p> <p>4 A. Yes.</p> <p>5 Q. I'm not -- just so you know, I'm not</p> <p>6 badgering you. Just sometimes the sound, I can't</p> <p>7 tell what you're saying.</p> <p>8 A. Oh, you didn't sound like you were</p> <p>9 badgering me that time.</p> <p>10 Q. I try to be clear when I am badgering.</p> <p>11 A. Okay.</p> <p>12 Q. When I'm badgering you, Mr. Combs turns</p> <p>13 red in the face.</p> <p>14 A. I'm not supposed to look at him.</p> <p>15 Q. Well, you will see the room glow if I'm</p> <p>16 doing my job.</p> <p>17 Let me ask you this. I think we might</p> <p>18 have touched on it earlier. I just want to be</p> <p>19 sure.</p> <p>20 Do you have an opinion based on any</p> <p>21 particular study of documents or any other</p> <p>22 information as to the size of the mesh pores in the</p> <p>23 Prolift when it's actually put into the body?</p> <p>24 A. No.</p> <p>25 Q. On page -- do you have your report</p>	<p style="text-align: right;">Page 148</p> <p>1 Q. Well, you took some data from a table</p> <p>2 that gave three-month data. What you didn't cite</p> <p>3 from that table was the 17% shrinkage rate. You</p> <p>4 didn't cite that in your report, correct?</p> <p>5 A. Correct.</p> <p>6 Q. You knew about the 17% shrinkage rate,</p> <p>7 correct?</p> <p>8 A. I read about the 17% shrinkage rate and</p> <p>9 I've always found it difficult to imagine how they</p> <p>10 measured it.</p> <p>11 Q. Are you saying that you don't believe</p> <p>12 that Jacquetin and Fatton and Cosson and the French</p> <p>13 TVM group could credibly document the shrinkage for</p> <p>14 their patients from the Prolift procedure that they</p> <p>15 created?</p> <p>16 A. No, I think these are very good</p> <p>17 researchers and they certainly know the product and</p> <p>18 have the most experience. I'm just never sure how</p> <p>19 to apply that kind of information clinically to my</p> <p>20 patients.</p> <p>21 Q. Did you make a conscious decision not to</p> <p>22 include the 17% shrinkage rate that was found in</p> <p>23 that study?</p> <p>24 A. No, I don't recall having that</p> <p>25 conversation with myself. It never came up should</p>
<p style="text-align: right;">Page 147</p> <p>1 handy?</p> <p>2 A. I should.</p> <p>3 Q. Look at page 12, please. Tell me when</p> <p>4 you're on page 12?</p> <p>5 A. I'm there.</p> <p>6 Q. On page 12 you cite to an article by</p> <p>7 Fatton, F-a-t-t-o-n, and some members of the TVM</p> <p>8 group regarding the Prolift, right?</p> <p>9 A. Right.</p> <p>10 Q. You cite some statistics that were</p> <p>11 reported, some data from that study, correct?</p> <p>12 A. Right.</p> <p>13 Q. Do you think it's important that when</p> <p>14 you cited data from a study in your report that you</p> <p>15 were evenhanded and cited the data that may be good</p> <p>16 or may be bad or vice versa?</p> <p>17 Let me ask it differently.</p> <p>18 Do you think it was important when you</p> <p>19 cited data in your report to be fair and balanced</p> <p>20 in how you did it to give a full view of the</p> <p>21 important data?</p> <p>22 A. I pulled up data that I recalled that I</p> <p>23 thought was important to know about Prolift. I</p> <p>24 wasn't looking for an equal amount of bad data or</p> <p>25 good data.</p>	<p style="text-align: right;">Page 149</p> <p>1 I include this or not. I looked at the information</p> <p>2 I thought was pertinent.</p> <p>3 Q. You would agree that the 17% shrinkage</p> <p>4 rate at three months is significant, correct?</p> <p>5 A. I don't know.</p> <p>6 Q. In this case where mesh</p> <p>7 shrinkage/contraction is the complication that was</p> <p>8 suffered by Ms. Bellew, wouldn't the 17% shrinkage</p> <p>9 rate found at three months by the inventors of the</p> <p>10 Prolift be of significance?</p> <p>11 MR. COMBS: Object to form.</p> <p>12 BY THE WITNESS:</p> <p>13 A. No.</p> <p>14 BY MR. SLATER:</p> <p>15 Q. Are you aware of any clinical data</p> <p>16 reported by the French TVM group regarding the</p> <p>17 percentage of women treated with Prolift suffering</p> <p>18 from painful mesh contraction due to the Prolift?</p> <p>19 A. I'm sure I have it. I don't have it at</p> <p>20 the tip of my brain now.</p> <p>21 Q. It's not cited anywhere in your report,</p> <p>22 correct?</p> <p>23 A. Right.</p> <p>24 Q. Are you familiar with the study authored</p> <p>25 by Velemir, Fatton, Jacquetin regarding ultrasound</p>

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<p style="text-align: right;">Page 150</p> <p>1 and tracking retraction of Prolift mesh?</p> <p>2 A. No.</p> <p>3 Q. On page 14 of your report you cite the</p> <p>4 Altman RCT from 2011 and you indicate that the</p> <p>5 patients who returned to surgery to treat mesh</p> <p>6 exposure was 3.2% of the patients, right?</p> <p>7 A. Correct.</p> <p>8 Q. There is no information in that article</p> <p>9 about the total erosion or exposure rate. They</p> <p>10 just tell the percentage that went back for</p> <p>11 surgery, right?</p> <p>12 A. That's right.</p> <p>13 Q. And they don't define surgery so you</p> <p>14 don't know if someone getting an operative</p> <p>15 procedure in an office versus a hospital was</p> <p>16 counted. We don't know that, right?</p> <p>17 A. Right. We don't know if it was or was</p> <p>18 not.</p> <p>19 Q. The Withagen study from 2011 you cited</p> <p>20 just below that on page 14. They found about 17%</p> <p>21 of the patients had mesh exposure, right, into the</p> <p>22 vagina?</p> <p>23 A. Right.</p> <p>24 Q. I'd like you to assume that there are --</p> <p>25 rephrase.</p>	<p style="text-align: right;">Page 152</p> <p>1 described in that article, the very severe</p> <p>2 complications described.</p> <p>3 MR. COMBS: Object to form.</p> <p>4 BY THE WITNESS:</p> <p>5 A. I would say, then, it depends on the</p> <p>6 rate. If it's a rare complication or not, it's</p> <p>7 hard to say how much information needs to go in the</p> <p>8 IFU.</p> <p>9 BY MR. SLATER:</p> <p>10 Q. So you can't form an opinion on that one</p> <p>11 way or another or you're saying -- rephrase.</p> <p>12 So, you're saying that information would</p> <p>13 need to be in the IFU if Ethicon knew it and knew</p> <p>14 it was going to happen to some women from the</p> <p>15 Prolift. Would you agree with that?</p> <p>16 MR. COMBS: Object to form.</p> <p>17 BY THE WITNESS:</p> <p>18 A. Again, I think I would not expect to</p> <p>19 read in an IFU every rare complication. It depends</p> <p>20 how much of a problem it's going to be clinically.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. Well, you don't know what the rate of</p> <p>23 the most severe life-changing complications from</p> <p>24 the Prolift is. You don't have that data, right?</p> <p>25 MR. COMBS: Object to form.</p>
<p style="text-align: right;">Page 151</p> <p>1 I'm going to talk to you about the</p> <p>2 Bandon article in the abstract a little bit with</p> <p>3 you. Okay?</p> <p>4 A. Okay.</p> <p>5 Q. I'd like you to assume for this question</p> <p>6 that Ethicon knew that there were doctors who would</p> <p>7 use the Prolift who would not have known that the</p> <p>8 very serious complications described in that</p> <p>9 article were potential risks with the Prolift, and</p> <p>10 I'd like you to assume Ethicon knew those risks as</p> <p>11 of the date the Prolift first went on the market.</p> <p>12 Okay?</p> <p>13 MR. COMBS: Object to the form.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Okay.</p> <p>16 Q. Do you understand my hypothetical?</p> <p>17 A. Yeah.</p> <p>18 Q. Assuming my hypothetical to be true,</p> <p>19 would you agree that those risks described in the</p> <p>20 Bandon article should have been disclosed in the</p> <p>21 IFU? Yes or no.</p> <p>22 A. That patients may have mesh exposures,</p> <p>23 contractions that require more than one surgery to</p> <p>24 fix?</p> <p>25 Q. The full scope of complications</p>	<p style="text-align: right;">Page 153</p> <p>1 BY THE WITNESS:</p> <p>2 A. Correct.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. If Ethicon knew that those very severe</p> <p>5 complications described in the Bandon article were</p> <p>6 going to happen to some patients due to the</p> <p>7 Prolift, they knew that, and they knew that would</p> <p>8 not be known by all of the doctors using the</p> <p>9 Prolift, would you agree with me in that</p> <p>10 circumstance that those risks of those very severe</p> <p>11 complications should have been disclosed in the</p> <p>12 IFU?</p> <p>13 A. No. And, again, because the IFU is not</p> <p>14 the only document we rely on and even the surgeons</p> <p>15 starting to use Prolift were -- were advised to be</p> <p>16 familiar with pelvic reconstructive surgery and use</p> <p>17 of permanent implants.</p> <p>18 So, I would expect that people using</p> <p>19 Prolift would know something about complications</p> <p>20 implanting mesh.</p> <p>21 MR. SLATER: Move to strike after "no."</p> <p>22 MR. COMBS: Adam, we have been going for over</p> <p>23 an hour now. Sometime in the next five minutes</p> <p>24 let's take a break.</p> <p>25 MR. SLATER: We can take a break right now.</p>

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<p>1 MR. COMBS: Okay.</p> <p>2 THE VIDEOGRAPHER: The time is 2:26 p.m. We</p> <p>3 are going off the video record.</p> <p>4 (WHEREUPON, a recess was had</p> <p>5 from 2:26 to 2:41 p.m.)</p> <p>6 THE VIDEOGRAPHER: The time is 2:41 p.m. and</p> <p>7 we are back on the video record.</p> <p>8 BY MR. SLATER:</p> <p>9 Q. Okay. Doctor, do I understand your</p> <p>10 testimony to be if there is something that Ethicon</p> <p>11 needed to tell surgeons about risks and</p> <p>12 complications about the Prolift and Ethicon failed</p> <p>13 to do so in the IFU, that's okay as long as they</p> <p>14 gave that information in the surgeons monograph?</p> <p>15 MR. COMBS: Object to the form.</p> <p>16 BY THE WITNESS:</p> <p>17 A. It's hard for me to answer that because</p> <p>18 you said if it's something that they need to tell</p> <p>19 surgeons. And that --</p> <p>20 Q. That's right because you only thought</p> <p>21 there was thing they needed to tell --</p> <p>22 A. Well, it's a bit subjective but the</p> <p>23 monograph was --</p> <p>24 Q. Let's talk about the monograph.</p> <p>25 A. Okay.</p>	<p>1 tension after closure of the incisions, that could</p> <p>2 increase the risk for complications, right?</p> <p>3 A. Yes.</p> <p>4 Q. You would also agree that even a doctor</p> <p>5 who is fully trained, follows the Prolift technique</p> <p>6 down to the T, can end up with tension on the mesh</p> <p>7 that can lead to complications, correct?</p> <p>8 A. Yes.</p> <p>9 Q. Is it your opinion that the surgeons</p> <p>10 monograph can be a substitute for the IFU in</p> <p>11 providing information about risks and complications</p> <p>12 to physicians?</p> <p>13 A. In clinical use, yes.</p> <p>14 Q. In terms of how the medical device</p> <p>15 company Ethicon is supposed to operate in the real</p> <p>16 world in providing information to doctors, was</p> <p>17 Ethicon allowed to provide information in a source</p> <p>18 other than the IFU even if that information</p> <p>19 belonged in the IFU?</p> <p>20 MR. COMBS: Object to the form.</p> <p>21 BY THE WITNESS:</p> <p>22 A. I don't know what they're allowed to do</p> <p>23 or supposed to do or what -- what federal rules or</p> <p>24 regulatory guidance applies. I know how surgeons</p> <p>25 get their information and it's not typically that</p>
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<p>1 Q. Do you know whether all the information</p> <p>2 in this monograph is true?</p> <p>3 A. I don't know. I'd be happy to go</p> <p>4 through it with you.</p> <p>5 Q. I don't want to go through it with you.</p> <p>6 I want to ask you. You're the expert. You listed</p> <p>7 this in your report and you've told me it's one of</p> <p>8 the few documents you're relying on.</p> <p>9 So, I'm asking you. Is all the</p> <p>10 information in the monograph true?</p> <p>11 A. I can't say it's all true. Certainly</p> <p>12 some of it's going to be opinion that's going to</p> <p>13 vary among surgeons. But largely it's a good place</p> <p>14 for surgeons to get information about this</p> <p>15 procedure.</p> <p>16 Q. Do you know what Ethicon Medical Affairs</p> <p>17 thought as to whether or not most doctors</p> <p>18 understood the tension-free concept in connection</p> <p>19 with the Prolift?</p> <p>20 A. No.</p> <p>21 Q. And you don't know whether most doctors</p> <p>22 understood it or not, right?</p> <p>23 A. Correct.</p> <p>24 Q. You would agree that if the tension-free</p> <p>25 concept was not understood and mesh ended up under</p>	<p>1 the IFU is their one and only go-to source. They</p> <p>2 would look to literature, experience, colleagues,</p> <p>3 monographs.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. Well, that's just the doctors you've</p> <p>6 spoken to and that you know, right?</p> <p>7 A. I can't know what every other doctor</p> <p>8 does, but I have interacted with doctors at all</p> <p>9 levels, in teaching institutions, at the</p> <p>10 preceptorships.</p> <p>11 Q. How many doctors have you spoken to</p> <p>12 about whether or not they read and rely on the IFU</p> <p>13 to tell them the risks or complications with a mesh</p> <p>14 kit? How many doctors have you had that specific</p> <p>15 conversation with?</p> <p>16 A. I may not have had that exact</p> <p>17 conversation. But I know from the preceptorships,</p> <p>18 interacting with dozens of surgeons wanting to</p> <p>19 bring vaginal mesh into their practice or</p> <p>20 specifically the Prolift into their practice, their</p> <p>21 main concern with IFU was procedural steps. This</p> <p>22 was not the document they looked to for</p> <p>23 complications.</p> <p>24 MR. SLATER: Move to strike from "but"</p> <p>25 forward.</p>

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<p style="text-align: right;">Page 158</p> <p>1 BY MR. SLATER:</p> <p>2 Q. Have you ever asked another doctor, "Do</p> <p>3 you look to the IFU to learn what the risks and</p> <p>4 complications of this procedure are" with regard to</p> <p>5 any particular kit? Have you ever asked a doctor</p> <p>6 that question?</p> <p>7 A. No.</p> <p>8 Q. You would agree with me that there is</p> <p>9 not data establishing that the use of topical</p> <p>10 estrogen has any true impact on whether or not a</p> <p>11 woman will have complications with the Prolift,</p> <p>12 correct?</p> <p>13 MR. COMBS: Object to form.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Correct.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. And you cannot say that if Ms. Bellew</p> <p>18 had used estrogen either more often or in different</p> <p>19 quantities that that would have prevented any of</p> <p>20 her complications, correct?</p> <p>21 A. No, we can't say for sure in this case,</p> <p>22 but we know that estrogen does seem to promote</p> <p>23 wound healing.</p> <p>24 Q. You can't say that the use of estrogen</p> <p>25 would have had any impact on the complications that</p>	<p style="text-align: right;">Page 160</p> <p>1 Prolift IFU?</p> <p>2 MR. COMBS: Object to the form.</p> <p>3 BY THE WITNESS:</p> <p>4 A. Again, I don't know that the</p> <p>5 complications need to be spelled out in the IFU</p> <p>6 from a clinical point of view.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. Just asking about that complication.</p> <p>9 What I just described, if Ethicon knew that, should</p> <p>10 they have warned about it in the IFU?</p> <p>11 A. No. Again, the IFU is more important</p> <p>12 clinically as a procedural guidance and there is</p> <p>13 other -- there is other areas where physicians get</p> <p>14 their information about the complications.</p> <p>15 Q. I think I understand you now. Let me</p> <p>16 ask you this. Tell me if I'm correct.</p> <p>17 A. Okay.</p> <p>18 Q. From your perspective the IFU is a</p> <p>19 source of information for doctors as to how to do</p> <p>20 the procedure. There are other places that doctors</p> <p>21 should go if they want to learn about the risks and</p> <p>22 complications of the procedure. Do I understand</p> <p>23 you?</p> <p>24 A. Yeah, there's other places they go.</p> <p>25 They rely on their experience, they rely on</p>
<p style="text-align: right;">Page 159</p> <p>1 Ms. Bellew had with the Prolift. That would be</p> <p>2 speculation, correct?</p> <p>3 A. Right. We cannot say for sure.</p> <p>4 Q. It would be speculative, correct?</p> <p>5 A. Yes, but the -- we believe it's such an</p> <p>6 important factor, we counsel our patients, we don't</p> <p>7 know for sure if you will heal better with estrogen</p> <p>8 but we advise you to use it to help prevent your</p> <p>9 chances from getting a complication.</p> <p>10 Q. Doctors tell patients to use the</p> <p>11 estrogen, but it's not been established that it</p> <p>12 actually helps to prevent Prolift complications,</p> <p>13 correct?</p> <p>14 A. I don't know of it being studied</p> <p>15 specifically preventing mesh complications.</p> <p>16 Q. Nothing you can point to, right?</p> <p>17 A. Correct.</p> <p>18 Q. I went through the -- let me ask you</p> <p>19 this: If Ethicon knew that in some women they</p> <p>20 could have Prolift complications, the women could</p> <p>21 go through multiple operations, and despite that,</p> <p>22 the complications could not be safely and</p> <p>23 effectively treated and the woman would be left</p> <p>24 with permanent and chronic pain, if Ethicon knew</p> <p>25 that, should they have warned about that in the</p>	<p style="text-align: right;">Page 161</p> <p>1 colleagues, they rely on conferences, literature.</p> <p>2 There's much more goes into it than the IFU</p> <p>3 stating --</p> <p>4 Q. So, from your perspective, from your</p> <p>5 perspective in your opinion, the purpose of the IFU</p> <p>6 is not to provide the risks and complications known</p> <p>7 to Ethicon regarding the Prolift to physicians.</p> <p>8 That's your perspective and your opinion, correct?</p> <p>9 A. That's my opinion and the Instructions</p> <p>10 for Use, how do I use this in the OR. That is how</p> <p>11 it's going -- I believe will be accepted by most</p> <p>12 surgeons. And you just gave me -- I want to do</p> <p>13 this study now. I'm going to survey all kinds of</p> <p>14 gynecologic surgeons to see if they even know what</p> <p>15 an IFU is.</p> <p>16 MR. SLATER: Move to strike from "that"</p> <p>17 forward.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. Let me ask you this. If Ethicon knew</p> <p>20 that some women would suffer complications from the</p> <p>21 Prolift that would be severe and that despite</p> <p>22 multiple operations the woman could not be safely</p> <p>23 and effectively treated and would be left with</p> <p>24 permanent chronic pain, if Ethicon knew that, would</p> <p>25 you agree with me they needed to get that</p>

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<p>1 information to physicians in some form, whether 2 through the IFU or some other document from 3 Ethicon, they needed to get that information to 4 doctors? 5 MR. COMBS: Object to form. 6 BY THE WITNESS: 7 A. Yes, we would like to have that 8 information. 9 BY MR. SLATER: 10 Q. With regard to all of the very serious 11 complications described in the Blandon article, 12 would you agree to the same thing, that Ethicon 13 needed to get that information to doctors in some 14 form if they knew those were going -- were risks 15 with the Prolift? 16 MR. COMBS: Object to the form. 17 BY THE WITNESS: 18 A. Well, I think that long list of 19 complications, some are not specific to Prolift. 20 There are complications of vaginal surgery, vaginal 21 mesh. 22 BY MR. SLATER: 23 Q. My question is if Ethicon Medical 24 Affairs has admitted that they knew that all of 25 those complications described in that article were</p>	<p>1 MR. SLATER: Move to -- move to strike after 2 the word "yes." 3 BY MR. SLATER: 4 Q. In essence your opinions about what 5 Ethicon needed to warn doctors about is not with 6 reference to any standards that actually exist in 7 the medical device world about what Ethicon was 8 required to do. You're just talking about 9 subjectively what you think the rules should be. 10 Correct? 11 MR. COMBS: Object to the form. 12 BY THE WITNESS: 13 A. Yes, I don't know what the regulatory 14 obligation of the company to notify surgeons is, 15 when the complication is serious enough or when 16 it's common enough. 17 But as a clinician who wants to know 18 about complications that are unique to a device, I 19 want that communicated in some way. 20 Now, if Ethicon has a laparoscopic 21 trocar and we find out you can put it in someone's 22 bellybutton and hit the aorta, is that something 23 the company needs to call and tell us about or put 24 in the IFU when it's a known risk of placing a 25 sharp instrument in the belly? It's a very serious</p>
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<p>1 risks with the Prolift, if they knew that, would 2 you agree they needed to get that information out 3 to surgeons, whether in the IFU or some other 4 document, so it would be available to doctors? 5 MR. COMBS: Object to the form. 6 BY THE WITNESS: 7 A. Again, I think physicians need to 8 understand the risk of surgery they're undertaking, 9 whether they are looking to the company to provide 10 that information or the literature, there is other 11 sources. 12 MR. SLATER: Move to strike. 13 BY MR. SLATER: 14 Q. My question is what the company needed 15 to do in your opinion. Do you agree that Ethicon, 16 if they had that information, needed to get that 17 out to surgeons either in the IFU or some other 18 document so that they would get that out to 19 doctors? Do you agree with that? 20 A. Yes, with the caveat that this 21 information is -- was frequently already out there 22 in the literature known to physicians. It's hard 23 to know when it's the company's job to say, hey, do 24 you know you can get a wound infection after you 25 make a wound. A lot of this --</p>	<p>1 complication. 2 MR. SLATER: Move to strike from "now" 3 forward. 4 BY MR. SLATER: 5 Q. When you give the opinion that the IFU 6 adequately warned surgeons of the potential risks 7 with the Prolift, which is the opinion in your 8 report, correct? 9 A. Correct. 10 Q. You're basing that opinion on your 11 foundational opinion that the IFU is not a place 12 where Ethicon was required to provide information 13 about risks and complications of the Prolift, 14 correct? 15 MR. COMBS: Object to form. 16 BY THE WITNESS: 17 A. They do warn of risks and complications 18 in the IFU. 19 BY MR. SLATER: 20 Q. That's not what I'm asking you. 21 A. Then can you ask me again. 22 Q. Is it your opinion that since Ethicon 23 didn't needed to provide information about risks 24 and complications in the IFU, whatever they 25 provided was adequate because they didn't need to</p>

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<p style="text-align: right;">Page 166</p> <p>1 provide that information to begin with?</p> <p>2 MR. COMBS: Object to form.</p> <p>3 BY THE WITNESS:</p> <p>4 A. They are -- I guess I need to ask you a</p> <p>5 clarifying question.</p> <p>6 If -- if there is an IFU out there and a</p> <p>7 complication gets reported, does it now need to get</p> <p>8 put into the IFU?</p> <p>9 BY MR. SLATER:</p> <p>10 Q. You're asking me that question?</p> <p>11 A. Yeah. I'm asking if that's what you're</p> <p>12 asking me.</p> <p>13 Q. You don't know -- that's not what I'm</p> <p>14 asking you. You don't know the answer to that</p> <p>15 question, do you? The one you just asked me you're</p> <p>16 asking because you don't know, right?</p> <p>17 A. Oh, I'm not doing your job.</p> <p>18 No, I want -- I want to know if that's</p> <p>19 what you're asking me. Are you talking about</p> <p>20 getting it into the IFU that's already out there or</p> <p>21 just the IFU from Day One?</p> <p>22 Q. Well, first of all, now that you ask me</p> <p>23 to clarify, first of all, from Day One.</p> <p>24 Is it your opinion the IFU adequately</p> <p>25 warned of the potential risks with the Prolift</p>	<p style="text-align: right;">Page 168</p> <p>1 Q. Again, in forming your opinions, you</p> <p>2 don't know what Ethicon's obligations were to warn,</p> <p>3 correct?</p> <p>4 A. Correct.</p> <p>5 Q. So, your opinions are not based on what</p> <p>6 Ethicon was obligated to do from any source, right?</p> <p>7 MR. COMBS: Object to the form.</p> <p>8 BY THE WITNESS:</p> <p>9 A. I -- my opinion is that as a surgeon who</p> <p>10 has -- who does pelvic reconstructive surgery and</p> <p>11 using mesh that what I expect the company put in</p> <p>12 the IFU to help me understand how to do pelvic</p> <p>13 reconstructive surgery with mesh may not include</p> <p>14 every single complication.</p> <p>15 MR. SLATER: Move to strike.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. All I'm saying is the opinions you're</p> <p>18 offering about the warnings are not based on any</p> <p>19 standard whatsoever as to what Ethicon was required</p> <p>20 to do because you don't know what they were</p> <p>21 required to do, right?</p> <p>22 A. No, I'm commenting on what the average</p> <p>23 pelvic surgeon needs to know.</p> <p>24 MR. SLATER: Move to strike.</p> <p>25 BY MR. SLATER:</p>
<p style="text-align: right;">Page 167</p> <p>1 since from your perspective Ethicon didn't need to</p> <p>2 warn of any risks anyway so whatever they put in</p> <p>3 there is more than they needed to do anyway?</p> <p>4 MR. COMBS: Object to the form.</p> <p>5 BY MR. SLATER:</p> <p>6 Q. Do I understand you?</p> <p>7 A. Yeah, and they did have warnings about</p> <p>8 the complications.</p> <p>9 Q. Do I understand -- so I understand your</p> <p>10 opinion, correct?</p> <p>11 A. Correct.</p> <p>12 Q. I'm going to ask you a different</p> <p>13 question now relating back to what you asked me.</p> <p>14 Once the IFU is out there, if Ethicon</p> <p>15 learned of a risk or a complication that was not</p> <p>16 previously warned about and it was a significant</p> <p>17 risk or complication in terms of the harm it could</p> <p>18 cause to a woman, do you know whether or not</p> <p>19 Ethicon had any obligation or have any opinion</p> <p>20 whether they had any obligation to get that</p> <p>21 information out to doctors?</p> <p>22 A. I don't know what the obligations are.</p> <p>23 So, do they get -- would it be updated on a regular</p> <p>24 time interval or is it depending on when</p> <p>25 complications happen?</p>	<p style="text-align: right;">Page 169</p> <p>1 Q. Is the answer to my question yes?</p> <p>2 MR. COMBS: Object to form.</p> <p>3 BY THE WITNESS:</p> <p>4 A. Yes.</p> <p>5 BY MR. SLATER:</p> <p>6 Q. I'd like you to assume -- no, I'll</p> <p>7 withdraw that. Just give me one second. I'm</p> <p>8 almost done.</p> <p>9 I didn't finish with your materials in</p> <p>10 your report. Let's go to the end of your report,</p> <p>11 the last two pages.</p> <p>12 The second-to-last page of your report</p> <p>13 of Attachment B is a list of expert reports,</p> <p>14 depositions, other and medical records.</p> <p>15 Do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. With regards to those categories of</p> <p>18 documents, that's all you saw. And, of course, the</p> <p>19 medical records go over to the next page. You</p> <p>20 didn't see any other expert reports, depositions or</p> <p>21 medical records, correct?</p> <p>22 A. I have since seen some more depositions</p> <p>23 and expert reports.</p> <p>24 Q. Did you read or rely on any of those</p> <p>25 depositions or expert reports?</p>

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<p>1 A. Not for this report, no, because I read 2 those afterwards. 3 Q. What I'm asking you is as you sit here 4 now, are you relying on any other depositions or 5 expert reports other than what's listed here for 6 your opinions? 7 A. No, I don't think so. 8 MR. SLATER: Hey, Phil. 9 MR. COMBS: Yes. 10 MR. SLATER: I know that a Deposition Notice 11 was served. My guess is your position is you will 12 respond to it in due course but not today? 13 MR. COMBS: Yeah, that's correct, Adam. And 14 we have brought the materials that Dr. Elser had 15 that would be responsive. But I'll tell you, other 16 than the case-specific stuff, it's the same stuff 17 that she brought when Tom Cartmell deposed her in 18 Edwards. You all have got it all. 19 Absolutely we are going to forward to 20 you the invoices and billing records. I asked 21 Dr. Elser this morning if she had prepared a bill 22 in Bellew. She hadn't. If you want to ask her 23 what the approximate total is going to be, please 24 feel free to do so. But we obviously will provide 25 that to you.</p>	<p>1 Q. Doctor, we've marked as Exhibit Elser 2 2 the article that you had mentioned to me earlier as 3 being in addition to what was on your -- listed in 4 your report. Can you just read the title of it 5 real quick? 6 A. It's called "Myofascial Pelvic Pain" and 7 the authors are Spitznagle and Robinson who are 8 both doctors of physical therapy and it was in 9 Ob-Gyn Clinics of North America published in 2014. 10 Q. March 14, this year? 11 A. In 2014. I don't have a month on it. 12 Q. Is that article of some significance to 13 you? 14 A. Oh, it talks about different treatments 15 for myofascial pelvic pain, including defining it 16 and what some symptoms might be and how to treat 17 it. 18 Q. Myofascial -- rephrase. 19 Myofascial pelvic pain like Ms. Bellew 20 has in your opinion can be treated with the types 21 of treatments described in that article and in some 22 women it will not resolve and remain a permanent 23 condition, right? 24 A. It can remain a chronic condition, yes. 25 Q. Now, can you give us -- I know that</p>
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<p>1 MR. SLATER: Let me tell you what I'd like to 2 do. To the extent the medical records are listed 3 in the expert report, I don't need to mark those. 4 To the extent -- I know that the article that was 5 mentioned earlier I'm going to need that and I 6 guess we forgot about it. But you can -- I'd like 7 to have that sent over to me. 8 MR. COMBS: Yes. 9 MR. SLATER: Do we know the title of it now? 10 MR. COMBS: Let's go ahead -- let's go off the 11 record just for a second off the video. Let's you 12 and I talk and we will assemble that. 13 THE VIDEOGRAPHER: The time is 3:02 p.m. and 14 we are going off the video record. 15 (WHEREUPON, discussion was had off 16 the record.) 17 THE VIDEOGRAPHER: The time is 3:05 and we are 18 back on the video record. 19 (WHEREUPON, a certain document was 20 marked Elser Deposition Exhibit 21 No. 2, article, "Myofascial Pelvic 22 Pain" by Spitznagle and Robinson, 23 for identification, as of 24 09/16/2014.) 25 BY MR. SLATER:</p>	<p>1 you're going to produce your invoices through 2 counsel to us and we just talked about that off the 3 video record. 4 But can you just give me the best 5 estimate you can of the amount of time you've spent 6 on this case and the amount of billing? 7 A. It will likely be between 100 to 130 8 hours. 9 Q. And what's your billing rate again? 10 A. 600 for the review and meetings and -- I 11 mean, 500 an hour and then 600 an hour for today. 12 Q. With regard to what was requested in 13 this Deposition Notice, it's my understanding that 14 you have with you obviously the article we just 15 marked, copies of the medical records listed in the 16 report, and anything else you have with you is 17 listed in the report already, correct? 18 A. I believe so. 19 Q. And we already went through at the 20 beginning of the deposition and even recently when 21 you talked about the recent materials, you've 22 already told me what it is you actually relied on 23 to form your opinions in this case, correct? 24 A. Yes. 25 MR. SLATER: I don't have any other questions.</p>

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<p>1 MR. COMBS: Adam, we are going to have some 2 redirect. It won't be extensive. Let's take about 3 a ten-minute break and then we'll come on and do 4 that. 5 MR. SLATER: Splendid. 6 THE VIDEOGRAPHER: The time is 3:07 p.m. and 7 we are going off the video record. 8 (WHEREUPON, a recess was had 9 from 3:07 to 3:29 p.m.) 10 THE VIDEOGRAPHER: The time is 3:29 p.m. and 11 we are back on the video record. 12 EXAMINATION 13 BY MR. COMBS: 14 Q. Dr. Elser, I'm going to ask you some 15 questions now. 16 Do you remember the questions that 17 Mr. Slater asked you regarding Ms. Bellew and 18 whether she presented with dyspareunia? 19 A. Yes. 20 Q. Now, in her deposition did Ms. Bellew 21 discuss presentation of dyspareunia prior to the 22 Prolift implantation? 23 A. At her deposition she was asked if she 24 talked with anyone about the upcoming surgery. 25 This was the initial implant surgery. And she said</p>	<p>1 regulations, are you? 2 A. No. 3 Q. And is your opinion regarding the IFU 4 based upon how an IFU is used by clinicians? 5 A. Yes. My interactions with clinicians 6 for a variety of procedures, at preceptorships, at 7 training residents, learning new procedures in the 8 OR. 9 Q. And have you reviewed the IFU that was 10 in place for Prolift at the time of Ms. Bellew's 11 surgery? 12 A. Yes, I have. 13 MR. COMBS: And we'll mark that as Elser 14 Exhibit 3. 15 (WHEREUPON, a certain document was 16 marked Elser Deposition Exhibit 17 No. 3, Gynecare Prolift IFU; Bates 18 Nos. ETH.MESH.02341454 - 02341459 19 for identification.) 20 BY MR. COMBS: 21 Q. And, Dr. Elser, is it your opinion that 22 this IFU adequately conveyed the risks to surgeons 23 that were using the Prolift system? 24 MR. SLATER: Objection. 25 BY THE WITNESS:</p>
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<p>1 she talked it over with her long-term boyfriend, 2 and the main thing they talked about was how long 3 it would be before she could have sex again and 4 that was an important issue because they had not 5 been able to have sex because it hurt. 6 Q. Now, Dr. Elser, have you conducted 7 surveys related to baseline dyspareunia rates of 8 the patients that present to you for 9 urogynecological treatment? 10 A. Yes, in 2009 I presented an abstract on 11 baseline sexual function of women presenting with 12 urogynecologic problems to our clinic. So, it was 13 all -- we took all new patients over a 12-month 14 period. And the baseline dyspareunia rate was 15 37 percent. 16 Q. And that was of the patients that 17 presented to you that -- that calendar year for 18 urogynecological treatment? 19 A. Right. That's all the new patients that 20 I saw in a calendar year. 21 Q. Dr. Elser, Mr. Slater asked you numerous 22 questions about the IFU. You are not an expert in 23 regulatory affairs, are you? 24 A. No. 25 Q. You're not an expert in government</p>	<p>1 A. So, this Prolift IFU has the list of 2 contraindications, warnings, precautions and 3 adverse reactions. And these were adequate, 4 included, carefully placing it to avoid damage to 5 vessels, nerves, bladder, bowel, what the patient 6 should avoid postoperatively, avoid placing excess 7 tension on the mesh implant during handling. 8 BY MR. COMBS: 9 Q. And during your testimony did you talk 10 several times about the fact that the IFU makes a 11 reference to surgeons that are implanting the 12 Prolift device should be surgeons who have used 13 this type of procedure before? 14 A. Yes. 15 MR. SLATER: Objection. 16 BY MR. COMBS: 17 Q. And does the IFU also make it clear on 18 the first page of it that training is recommended 19 and available for Prolift? 20 A. Yes, it does. 21 MR. SLATER: Objection. 22 BY MR. COMBS: 23 Q. And did you participate in that prof ed 24 training? 25 A. Yes, I did.</p>

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<p>1 Q. Now, is your opinion based upon the</p> <p>2 adequacy of the IFU based upon other things in</p> <p>3 addition to the review of the IFU?</p> <p>4 MR. SLATER: Objection.</p> <p>5 BY THE WITNESS:</p> <p>6 A. Yes, because the training was offered.</p> <p>7 It was offered with -- in a didactic cadaver lab to</p> <p>8 go see someone with more experience use the product</p> <p>9 for the first time and to have a surgeon come to</p> <p>10 the hospital to be there to observe the first few</p> <p>11 cases.</p> <p>12 BY MR. COMBS:</p> <p>13 Q. And have you had -- well, strike that.</p> <p>14 Is your opinion regarding the risk</p> <p>15 information that was conveyed to surgeons also</p> <p>16 based upon your review of the clinical literature?</p> <p>17 A. Yes.</p> <p>18 MR. SLATER: Objection.</p> <p>19 BY MR. COMBS:</p> <p>20 Q. Is it also based upon your membership in</p> <p>21 professional societies?</p> <p>22 MR. SLATER: Objection.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Yes.</p> <p>25 BY MR. COMBS:</p>	<p>1 Q. And have you used IFUs in your clinical</p> <p>2 practice?</p> <p>3 A. I have.</p> <p>4 Q. And was it your testimony that you read</p> <p>5 this IFU at the time that it came out and that when</p> <p>6 you were using the Prolift device?</p> <p>7 A. Yes.</p> <p>8 MR. SLATER: Objection.</p> <p>9 BY MR. COMBS:</p> <p>10 Q. You talked earlier about what are some</p> <p>11 of the complications that are set forth in the IFU?</p> <p>12 A. It does talk about adverse reactions.</p> <p>13 So, typically associated with surgical implantable</p> <p>14 materials, infection potentiation, inflammation,</p> <p>15 adhesion, fistula, erosion, extrusion and scarring</p> <p>16 that results in implant contraction, besides injury</p> <p>17 to vessels, nerves, bladder, urethra or bowel.</p> <p>18 Q. Now, Dr. Elser, can any of the</p> <p>19 conditions that are set forth in this IFU lead to</p> <p>20 the development of dyspareunia?</p> <p>21 MR. SLATER: Objection.</p> <p>22 BY THE WITNESS:</p> <p>23 A. Yes.</p> <p>24 BY MR. COMBS:</p> <p>25 Q. And is that a fact that would be known</p>
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<p>1 Q. And is it also based upon your</p> <p>2 interaction with other physicians?</p> <p>3 MR. SLATER: Objection.</p> <p>4 BY THE WITNESS:</p> <p>5 A. Yes.</p> <p>6 BY MR. COMBS:</p> <p>7 Q. And can you explain to the Court or to</p> <p>8 the jury, when you say that, what interaction are</p> <p>9 you talking about?</p> <p>10 A. Well, there is not only interactions</p> <p>11 with other members of societies like AUGS, SGS,</p> <p>12 IUGA, but after the preceptorships, both when I</p> <p>13 went as a student learning the procedure and as a</p> <p>14 preceptor, the information of the trainer's contact</p> <p>15 info was provided and freely encouraged anyone who</p> <p>16 had received training, call us at any time. Call</p> <p>17 if you have question about a patient's post-op</p> <p>18 course, about if you should decide which patient to</p> <p>19 implant this on. We as preceptors now are</p> <p>20 available to you.</p> <p>21 That was not -- there was no clock</p> <p>22 running with you're getting paid for that. This</p> <p>23 was something we were happy to do to help other</p> <p>24 physicians understand how to use mesh to best take</p> <p>25 care of patients and how to manage any problems.</p>	<p>1 to pelvic floor surgeons?</p> <p>2 A. Yes.</p> <p>3 MR. SLATER: Objection.</p> <p>4 BY THE WITNESS:</p> <p>5 A. Dyspareunia after pelvic surgery would</p> <p>6 be known to pelvic floor surgeons.</p> <p>7 BY MR. COMBS:</p> <p>8 Q. And, in fact, that's a risk of any</p> <p>9 pelvic floor surgery, isn't it?</p> <p>10 MR. SLATER: Objection.</p> <p>11 BY THE WITNESS:</p> <p>12 A. That would be a risk of any pelvic floor</p> <p>13 surgery.</p> <p>14 BY MR. COMBS:</p> <p>15 Q. And that would be -- that would be a</p> <p>16 fact that would be known by any surgeon who was</p> <p>17 doing pelvic floor reconstructive surgery, wouldn't</p> <p>18 it?</p> <p>19 A. Yes.</p> <p>20 MR. SLATER: Objection.</p> <p>21 BY MR. COMBS:</p> <p>22 Q. Now, Dr. Elser, have you had occasion to</p> <p>23 talk with other surgeons regarding the Prolift IFU?</p> <p>24 MR. SLATER: Objection.</p> <p>25 BY THE WITNESS:</p>

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<p>1 A. I have.</p> <p>2 BY MR. COMBS:</p> <p>3 Q. And can you tell us what situations that</p> <p>4 arose in?</p> <p>5 A. For the most part it would be at the</p> <p>6 preceptorships, people attending, learning how to</p> <p>7 do the procedure, would have a lot of questions</p> <p>8 about the procedural steps. I want to take an IFU</p> <p>9 with me for maybe I'm not going to do my first case</p> <p>10 until a couple months after training to remember</p> <p>11 the procedural steps.</p> <p>12 But in follow-up in many courses and</p> <p>13 cadaver labs, I've never heard a surgeon say, "Boy,</p> <p>14 I wish I hadn't use that product" -- "I wish this</p> <p>15 would have been in the IFU. If I had read this</p> <p>16 particular complication in the IFU I never would</p> <p>17 have used a product," I have never heard as a</p> <p>18 criticism of the IFU.</p> <p>19 Q. When you're talking about criticism in</p> <p>20 the IFU, are you talking about the Prolift IFU?</p> <p>21 A. Yes.</p> <p>22 MR. SLATER: Objection.</p> <p>23 BY MR. COMBS:</p> <p>24 Q. Now, you've told us briefly but what are</p> <p>25 the other sources of information by which surgeons</p>	<p>1 Q. And is that one of the documents --</p> <p>2 MR. SLATER: Objection.</p> <p>3 BY MR. COMBS:</p> <p>4 Q. -- that you relied upon in forming your</p> <p>5 opinions in this case?</p> <p>6 A. Yes.</p> <p>7 MR. SLATER: Objection.</p> <p>8 BY MR. COMBS:</p> <p>9 Q. Dr. Elser, have you reviewed the</p> <p>10 specific warnings that Dr. DeHasse gave Mrs. Bellew</p> <p>11 in this case?</p> <p>12 A. Yes, I have.</p> <p>13 Q. And what did those warnings indicate to</p> <p>14 you that Dr. DeHasse understood about this</p> <p>15 procedure?</p> <p>16 A. I believe she talked about pain,</p> <p>17 scarring and dyspareunia as risk factors.</p> <p>18 Q. And what did you take from that?</p> <p>19 A. That Dr. DeHasse was aware that these</p> <p>20 could be the outcome after a vaginal prolapse</p> <p>21 procedure using mesh.</p> <p>22 Q. And as you testified earlier, those</p> <p>23 would be facts that any pelvic floor reconstructive</p> <p>24 surgeon would know, aren't they?</p> <p>25 A. Yes.</p>
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<p>1 learn risks?</p> <p>2 MR. SLATER: Objection.</p> <p>3 BY THE WITNESS:</p> <p>4 A. It's going to be in training, whether</p> <p>5 that's residency, fellowship training, in practice,</p> <p>6 and speaking with colleagues and reading the</p> <p>7 literature, attending conferences and</p> <p>8 presentations.</p> <p>9 BY MR. COMBS:</p> <p>10 Q. Do you have any firsthand knowledge of</p> <p>11 Ethicon's professional education that was offered</p> <p>12 to supplement surgeons training with Prolift?</p> <p>13 MR. SLATER: Objection.</p> <p>14 BY THE WITNESS:</p> <p>15 A. There were slide decks and reps would --</p> <p>16 always had slide decks to hand out or videos.</p> <p>17 Monograph was available. The Instructions for Use</p> <p>18 were available, brochures were available and</p> <p>19 reproductions of any literature that was</p> <p>20 relative -- relevant.</p> <p>21 BY MR. COMBS:</p> <p>22 Q. And as you testified earlier, is the</p> <p>23 monograph that you're referring to the Surgeons'</p> <p>24 Resource Monograph?</p> <p>25 A. Yes.</p>	<p>1 MR. SLATER: Objection.</p> <p>2 BY MR. COMBS:</p> <p>3 Q. Dr. Elser, Mr. Slater asked you</p> <p>4 questions about long-term pain after Prolift. Do</p> <p>5 you remember those questions?</p> <p>6 A. Yes, I do.</p> <p>7 Q. I want to ask you some questions about</p> <p>8 contraction at the mesh arms which Mr. Slater asked</p> <p>9 you about. Have you ever experienced this in any</p> <p>10 of your patients?</p> <p>11 A. Yes, I have.</p> <p>12 Q. And was that a risk that you were aware</p> <p>13 of before implanting the Prolift device?</p> <p>14 A. Yes.</p> <p>15 MR. SLATER: Objection.</p> <p>16 BY MR. COMBS:</p> <p>17 Q. How did you know that?</p> <p>18 A. We talked about it at the initial</p> <p>19 training. It was talked about not to place the</p> <p>20 mesh under excessive tension, which is also</p> <p>21 included in the monograph, to avoid tension on the</p> <p>22 mesh arms and help avoid contraction, pain at the</p> <p>23 contraction site.</p> <p>24 Q. And can you explain briefly how placing</p> <p>25 the mesh with improper tension would increase the</p>

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<p style="text-align: right;">Page 186</p> <p>1 risk of contraction at the mesh arm?</p> <p>2 MR. SLATER: Objection.</p> <p>3 BY THE WITNESS:</p> <p>4 A. The mesh is placed typically with a</p> <p>5 patient under general anesthetic and in a supine</p> <p>6 position so we know that even immediately when that</p> <p>7 patient wakes up and stands up, no longer has</p> <p>8 muscle relaxant in her system and she now stands up</p> <p>9 and puts pressure on her pelvic floor, that there</p> <p>10 is immediately going to be some uptake, some</p> <p>11 increase in tension on the mesh that's placed.</p> <p>12 That's even before she starts having</p> <p>13 more daily activities of lifting, exercise,</p> <p>14 intercourse, bowel movements. So, it has to be</p> <p>15 placed without tension, in fact, with a little</p> <p>16 laxity to it, to allow for that change.</p> <p>17 Q. Did Dr. DeHase testify in her</p> <p>18 deposition that she in fact did place the mesh</p> <p>19 under tension?</p> <p>20 MR. SLATER: Objection.</p> <p>21 BY THE WITNESS:</p> <p>22 A. She describes pulling the mesh arms</p> <p>23 until the mesh laid flat. And I was taught</p> <p>24 initially and I always taught that you want to</p> <p>25 leave it kind of like your teenager would throw</p>	<p style="text-align: right;">Page 188</p> <p>1 physical therapy, use of muscle relaxants such as</p> <p>2 benzodiazepine like Valium and typically we'll</p> <p>3 advise patients to use that vaginally, not by</p> <p>4 mouth, so they don't have systemic side effects.</p> <p>5 We may use a different type of</p> <p>6 antidepressant like amitriptyline, which helps with</p> <p>7 neuropathic myofascial pain.</p> <p>8 And then direct injections into the</p> <p>9 muscle usually with a local anesthetic and perhaps</p> <p>10 a steroid but sometimes just dry needling those</p> <p>11 muscles will get them to relax.</p> <p>12 Q. And have you reviewed Dr. Elliott's</p> <p>13 examination that he conducted in May of</p> <p>14 Mrs. Bellew?</p> <p>15 A. Yes, I did.</p> <p>16 Q. And at that time did Dr. Elliott find</p> <p>17 Mrs. -- strike that.</p> <p>18 At that time did Mrs. Bellew relate</p> <p>19 complaints to Dr. Elliott related to the mesh arms?</p> <p>20 A. No. He stated that she did not tolerate</p> <p>21 the exam well, that she had introital pain and</p> <p>22 winced and retracted from the examining finger. He</p> <p>23 had difficulty putting a speculum in from tightness</p> <p>24 at the introitus, which is not near the mesh arms.</p> <p>25 He palpated along the left sulcus. He</p>
<p style="text-align: right;">Page 187</p> <p>1 their comforter on a bed, really loose with lots of</p> <p>2 ripples on it.</p> <p>3 BY MR. COMBS:</p> <p>4 Q. When you have had patients in your</p> <p>5 practice that have had contraction at the mesh arm,</p> <p>6 how have you treated those?</p> <p>7 A. So, patients with contraction at the</p> <p>8 mesh arm, first of all, we want to distinguish is</p> <p>9 it symptomatic or not. If it's something I find on</p> <p>10 exam but the patient has no pain, it's not</p> <p>11 necessarily going to require treatment.</p> <p>12 If it's causing problems for the</p> <p>13 patient, however, because the mesh arm is connected</p> <p>14 to the obturator which is connected to pelvic</p> <p>15 muscles, I want to check for pelvic floor tension,</p> <p>16 myofascial problems and then if we can get those</p> <p>17 muscles to relax, that may ease up all the tension</p> <p>18 and a mesh band may no longer be felt. So, it may</p> <p>19 not be just fibrosis and scarring. It may be</p> <p>20 tension from the muscles nearby pulling on it.</p> <p>21 Q. And --</p> <p>22 A. So, the first line is not surgical.</p> <p>23 Q. And what are some of the alternative</p> <p>24 therapies that you would use?</p> <p>25 A. So, therapies we'll use are pelvic floor</p>	<p style="text-align: right;">Page 189</p> <p>1 describes a tenderness along the left sulcus but</p> <p>2 that no mesh band is palpable in this area.</p> <p>3 Q. Dr. Elser, I want to ask you some</p> <p>4 questions about Mrs. Bellew's clinical</p> <p>5 presentation. When -- strike that.</p> <p>6 Mr. Slater asked you some questions</p> <p>7 about Mrs. Bellew's presentation and whether she</p> <p>8 exhibited pain. Did other records in addition to</p> <p>9 the one that Mr. Slater reviewed with you indicate</p> <p>10 that Mrs. Bellew did present with pain prior to the</p> <p>11 implant surgery?</p> <p>12 MR. SLATER: Objection.</p> <p>13 BY THE WITNESS:</p> <p>14 A. Yes, there was a note from her primary</p> <p>15 care doctor, Dr. Leano, they had talked about she</p> <p>16 had been to the ER with abdominal and pelvic pain.</p> <p>17 BY MR. COMBS:</p> <p>18 Q. Now, Mr. Slater asked you questions</p> <p>19 about whether she showed signs of incontinence.</p> <p>20 Were there in fact other records that did indicate</p> <p>21 that she was exhibiting incontinence at the time of</p> <p>22 the Prolift implantation?</p> <p>23 MR. SLATER: Objection, ambiguous.</p> <p>24 BY THE WITNESS:</p> <p>25 A. One of the notes before the surgery from</p>

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<p style="text-align: right;">Page 190</p> <p>1 the primary care doctor's office did state she had</p> <p>2 complained of leaking with cough and then</p> <p>3 Dr. DeHasse on the initial visit prescribed</p> <p>4 oxybutynin, which is an oral anticholinergic</p> <p>5 medication used to treat overactive bladder or urge</p> <p>6 incontinence.</p> <p>7 BY MR. COMBS:</p> <p>8 Q. And the indication for that medication</p> <p>9 would be from a patient suffering from urge</p> <p>10 incontinence?</p> <p>11 MR. SLATER: Objection.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Urge incontinence, frequency, nocturia.</p> <p>14 BY MR. COMBS:</p> <p>15 Q. Now, Mr. Slater asked you some questions</p> <p>16 regarding whether Mrs. Bellew suffered from pelvic</p> <p>17 floor muscle spasm. Do you remember those</p> <p>18 questions?</p> <p>19 A. Yes.</p> <p>20 Q. Now, did Dr. DeHasse evaluate</p> <p>21 Mrs. Bellew for pelvic floor muscle spasm prior to</p> <p>22 the implant?</p> <p>23 A. I don't believe she evaluated it. If</p> <p>24 she did, it's not mentioned whether the muscles</p> <p>25 were normal tone, hypertonic, tender or not.</p>	<p style="text-align: right;">Page 192</p> <p>1 area are more prone to be hypersensitive and</p> <p>2 develop myofascial pain in other parts of the body.</p> <p>3 And in addition she's a smoker, and</p> <p>4 people who have a chronic cough from -- associated</p> <p>5 with smoking are putting pressure on their pelvic</p> <p>6 floor and they are more likely to have pelvic floor</p> <p>7 muscle tension.</p> <p>8 Q. And she had in fact suffered from a</p> <p>9 prolapse, hadn't she?</p> <p>10 A. Yes.</p> <p>11 Q. And is that also an indication that she</p> <p>12 could have pelvic floor muscle issues?</p> <p>13 A. Yes, it is. She has dysfunctional</p> <p>14 pelvic floor muscles.</p> <p>15 Q. What did you take away from the fact</p> <p>16 that Mrs. Bellew presented to the ER with pain as a</p> <p>17 result of a grade 2 cystocele?</p> <p>18 A. Having the primary presenting</p> <p>19 complaint --</p> <p>20 MR. SLATER: Objection.</p> <p>21 BY THE WITNESS:</p> <p>22 A. -- for grade 2 cystocele is incredibly</p> <p>23 unusual. Usually patients with a cystocele sitting</p> <p>24 right at the introitus, which is what a grade 2 is,</p> <p>25 will present with, oh, a typical example is I took</p>
<p style="text-align: right;">Page 191</p> <p>1 Q. And so there is no record from</p> <p>2 Dr. DeHasse that she made that evaluation and ruled</p> <p>3 that out, is there?</p> <p>4 A. No.</p> <p>5 MR. SLATER: Objection.</p> <p>6 BY MR. COMBS:</p> <p>7 Q. Now, did Mrs. Bellew suffer from risk</p> <p>8 factors for pelvic floor muscle spasm?</p> <p>9 A. Yes, she did.</p> <p>10 Q. And what are those risk factors?</p> <p>11 A. She suffered from chronic --</p> <p>12 Q. Well, strike that.</p> <p>13 I want to ask you now about risk factors</p> <p>14 that she presented with prior to the Prolift</p> <p>15 implant.</p> <p>16 A. Okay.</p> <p>17 Q. Did she suffer from risk factors prior</p> <p>18 to the Prolift implant?</p> <p>19 A. Yes.</p> <p>20 MR. SLATER: Objection.</p> <p>21 BY THE WITNESS:</p> <p>22 A. Primarily she had chronic pain that was</p> <p>23 myofascial which was related to her neck and back.</p> <p>24 She's using chronic narcotics for that. So,</p> <p>25 patients who have chronic myofascial pain in one</p>	<p style="text-align: right;">Page 193</p> <p>1 a shower today and I went to dry myself and I</p> <p>2 noticed something there that shouldn't be there.</p> <p>3 Then I looked in the mirror and I saw something.</p> <p>4 But pain is not typically the presenting</p> <p>5 complaint with rare exceptions. Sometimes there is</p> <p>6 a very large grade 2 cystocele that's under high</p> <p>7 tension and feels like a water balloon that wants</p> <p>8 to burst. The ligaments and muscles are under so</p> <p>9 much tension from this impending further prolapse,</p> <p>10 but it's usually so -- such a dramatic finding that</p> <p>11 I would expect to hear something about that in the</p> <p>12 description of the exam.</p> <p>13 Q. Now, these risk factors that Mrs. Bellew</p> <p>14 exhibited for pelvic floor muscle spasm prior to</p> <p>15 the Prolift implant, are those risk factors that</p> <p>16 you have seen other patients that you have treated</p> <p>17 clinically?</p> <p>18 MR. SLATER: Objection.</p> <p>19 BY THE WITNESS:</p> <p>20 A. Yes. Oh, let me add to the risk</p> <p>21 factors. She is on narcotics. So, most of our</p> <p>22 patients on chronic narcotics are constipated and</p> <p>23 straining. It's not necessarily something that's</p> <p>24 routinely screened for in patients with prolapse</p> <p>25 but needs to be.</p>

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<p>1 BY MR. COMBS:</p> <p>2 Q. And she also has presented with back</p> <p>3 pain, is that correct?</p> <p>4 A. Yes.</p> <p>5 MR. SLATER: Objection.</p> <p>6 BY MR. COMBS:</p> <p>7 Q. And is that also indicative -- or strike</p> <p>8 that.</p> <p>9 Can back pain also be a potential cause</p> <p>10 of pelvic floor muscle spasm?</p> <p>11 A. Absolutely.</p> <p>12 MR. SLATER: Objection.</p> <p>13 BY MR. COMBS:</p> <p>14 Q. Why is that?</p> <p>15 A. Our lower back muscles are connected to</p> <p>16 our pelvic muscles and tension in one may cause</p> <p>17 tension in the other or the back pain may be</p> <p>18 resulting from a disk problem, spinal stenosis, and</p> <p>19 those nerves are going to affect the pelvic floor</p> <p>20 muscle tone.</p> <p>21 Q. And these opinions that you have</p> <p>22 regarding Ms. Bellew's risk factors for pelvic</p> <p>23 floor muscle spasm, what are they based on?</p> <p>24 A. They are based on clinical experience,</p> <p>25 but there is also literature dating back as early</p>	<p>1 Q. Now, Dr. Elser, did Mrs. Bellew have a</p> <p>2 concomitant vaginal procedure of a hysterectomy at</p> <p>3 the same time that she had the Prolift implant?</p> <p>4 MR. SLATER: Objection.</p> <p>5 BY THE WITNESS:</p> <p>6 A. Yes, she did.</p> <p>7 BY MR. COMBS:</p> <p>8 Q. And what risks were presented by that</p> <p>9 vaginal hysterectomy?</p> <p>10 A. Having a hysterectomy at the same time</p> <p>11 increases the risk of granulation tissue and mesh</p> <p>12 erosion exposure.</p> <p>13 Q. And did that vaginal hysterectomy also</p> <p>14 independently present the risk of -- the risks that</p> <p>15 you have talked about here today regarding pelvic</p> <p>16 floor surgeries?</p> <p>17 MR. SLATER: Objection.</p> <p>18 BY THE WITNESS:</p> <p>19 A. Patients undergoing a simple vaginal</p> <p>20 hysterectomy can have dyspareunia and myofascial</p> <p>21 pain after.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. And is it your belief that</p> <p>24 Mrs. Bellew -- Ms. Bellew's hysterectomy would be a</p> <p>25 contributing cause of the pelvic floor -- strike</p>
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<p>1 as 2005 in the Ob-Gyn general literature describing</p> <p>2 the importance of evaluation of muscle tone in</p> <p>3 patients with prolapse both to see if they have</p> <p>4 weak muscles and could use some pelvic muscle</p> <p>5 strengthening exercises or to see if they have</p> <p>6 chronic constipation and pelvic floor muscle spasm</p> <p>7 and need down training.</p> <p>8 Q. And you have treated other patients that</p> <p>9 have presented with these same or similar symptoms.</p> <p>10 A. Yes.</p> <p>11 Q. And have those other patients also</p> <p>12 exhibited pelvic floor muscle spasm?</p> <p>13 A. Yes.</p> <p>14 Q. And is that the basis for your finding</p> <p>15 that Mrs. Bellew could have been suffering from</p> <p>16 pelvic floor muscle spasm prior to the Prolift</p> <p>17 surgery?</p> <p>18 A. Yes.</p> <p>19 MR. SLATER: Objection.</p> <p>20 BY MR. COMBS:</p> <p>21 Q. Are there any other bases for that</p> <p>22 finding?</p> <p>23 A. No. It's experience. Pelvic pain is</p> <p>24 frequently the cause especially when the degree of</p> <p>25 cystocele cannot explain the symptoms.</p>	<p>1 that.</p> <p>2 Is it your belief that Mrs. Bellew's</p> <p>3 vaginal hysterectomy would be a contributing cause</p> <p>4 of any pain that she is suffering now?</p> <p>5 MR. SLATER: Objection.</p> <p>6 BY THE WITNESS:</p> <p>7 A. It could be.</p> <p>8 BY MR. COMBS:</p> <p>9 Q. Dr. Elser, what do you believe is</p> <p>10 causing the pain that Mrs. Bellew claims to</p> <p>11 currently experience?</p> <p>12 A. Well, based on Dr. Elliott's exam, which</p> <p>13 is the last pelvic exam of record we have, she no</p> <p>14 longer had pain at the mesh site that had been</p> <p>15 excised. That mesh tension was relieved. There</p> <p>16 was some tenderness along the sulcus. But if</p> <p>17 there's also myofascial tenderness, which there was</p> <p>18 on this exam, and that's untreated, it's impossible</p> <p>19 to say if that sulcus pain would be there once the</p> <p>20 muscle pain was resolved because it likely would</p> <p>21 be.</p> <p>22 If we take the pressure off that sulcus,</p> <p>23 by letting the muscles soften, have less spasm, the</p> <p>24 pain may very well be resolved and find there that</p> <p>25 is no residual scar causing a problem.</p>

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<p style="text-align: right;">Page 198</p> <p>1 Q. Now, Mr. Slater asked you a number of</p> <p>2 questions about whether surgeries can cause</p> <p>3 permanent myofascial pain. Do you remember those</p> <p>4 questions?</p> <p>5 A. Yes.</p> <p>6 Q. Now, do surgeries of the type that</p> <p>7 Mrs. Bellew had raise the risk of permanent</p> <p>8 myofascial pain?</p> <p>9 MR. SLATER: Objection.</p> <p>10 BY THE WITNESS:</p> <p>11 A. Once she had the contraction band at the</p> <p>12 mesh arm identified and that was surgically</p> <p>13 excised, that surgical excision was a minor</p> <p>14 procedure. Yes, she did have three of them, but</p> <p>15 each time it was an incision over the scar band.</p> <p>16 The mesh was dissected out and removed where it was</p> <p>17 palpated to be in a scar band. That in and of</p> <p>18 itself would be more likely to relieve the</p> <p>19 myofascial tension than to cause it.</p> <p>20 BY MR. COMBS:</p> <p>21 Q. And that would not be more likely than</p> <p>22 not to be a cause of permanent myofascial pain in</p> <p>23 Mrs. Bellew's pelvic floor, would it?</p> <p>24 A. Correct.</p> <p>25 MR. SLATER: Objection.</p>	<p style="text-align: right;">Page 200</p> <p>1 Q. And does the use of a trocar make a</p> <p>2 procedure unsafe?</p> <p>3 A. No. One has to know the anatomy where</p> <p>4 the trocar is being placed and how to pass it in</p> <p>5 the safest way possible.</p> <p>6 MR. SLATER: I just want to interject. It's</p> <p>7 five of. You have got -- you have left me a lot of</p> <p>8 stuff to cover. I just want to let you know that.</p> <p>9 MR. COMBS: Okay.</p> <p>10 BY MR. COMBS:</p> <p>11 Q. Mr. Slater asked you questions regarding</p> <p>12 your use of Prolift. At the time the Prolift was</p> <p>13 decommercialized, were you still using it?</p> <p>14 A. Yes. I had in fact a few cases</p> <p>15 scheduled the week that it was announced that it</p> <p>16 was no longer being supported and so made a</p> <p>17 decision to change those patients to other</p> <p>18 procedures.</p> <p>19 Q. So, at that time it was still a</p> <p>20 procedure that you were offering to your patients</p> <p>21 and using in your patients?</p> <p>22 A. Yes.</p> <p>23 MR. SLATER: Objection. Leading.</p> <p>24 BY MR. COMBS:</p> <p>25 Q. Dr. Elser, the risks that you have</p>
<p style="text-align: right;">Page 199</p> <p>1 BY MR. COMBS:</p> <p>2 Q. Dr. Elser, have you reached opinions</p> <p>3 regarding Mrs. Bellew's preexisting disability?</p> <p>4 A. As far as we can tell from the records</p> <p>5 and her -- her testimony, she was declared disabled</p> <p>6 after her neck injury and her cervical spine</p> <p>7 surgery.</p> <p>8 Q. And those are set forth in your report?</p> <p>9 A. Yes.</p> <p>10 Q. Dr. Elser, Mr. Slater asked you some</p> <p>11 questions about trocar passage. Do you remember</p> <p>12 those questions?</p> <p>13 A. Yes.</p> <p>14 Q. Do pelvic floor surgeons use other</p> <p>15 procedures and devices that involve trocars?</p> <p>16 A. Yes.</p> <p>17 MR. SLATER: Objection.</p> <p>18 BY THE WITNESS:</p> <p>19 A. We have performed traditional slings and</p> <p>20 needle suspensions using trocars that are passed</p> <p>21 through small incisions through the pelvis.</p> <p>22 BY MR. COMBS:</p> <p>23 Q. And how long have pelvic floor surgeons</p> <p>24 been using devices that involve trocars?</p> <p>25 A. Decades.</p>	<p style="text-align: right;">Page 201</p> <p>1 discussed related to Prolift, with the exception of</p> <p>2 exposure, are those risks that are present with all</p> <p>3 pelvic floor surgeries?</p> <p>4 MR. SLATER: Objection.</p> <p>5 BY THE WITNESS:</p> <p>6 A. Exposure and then the specific</p> <p>7 tenderness at the mesh arms is a risk unique to</p> <p>8 Prolift as opposed to mesh that does not have arms.</p> <p>9 BY MR. COMBS:</p> <p>10 Q. And Mrs. Bellew did not have an exposure</p> <p>11 or erosion, did she?</p> <p>12 A. No.</p> <p>13 Q. And the risks that you've discussed of</p> <p>14 potential scarring, is that also a risk that is</p> <p>15 equally presented with native tissue repairs?</p> <p>16 A. Patients --</p> <p>17 MR. SLATER: Objection.</p> <p>18 BY THE WITNESS:</p> <p>19 A. Patients undergoing any prolapse surgery</p> <p>20 can have scarring and pain.</p> <p>21 BY MR. COMBS:</p> <p>22 Q. Including abdominal sacrocolpopexy?</p> <p>23 A. Yes.</p> <p>24 MR. SLATER: Objection.</p> <p>25 MR. COMBS: Let's take a break for a minute,</p>

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<p>1 Adam. I'm going to see if I have anything else and 2 then you can do your redirect. 3 MR. SLATER: You asked a lot of questions and 4 I need to finish today. 5 MR. COMBS: Okay. Thank you. 6 THE VIDEOGRAPHER: The time is 3:57 p.m. This 7 is the end of Tape 2 and we are going off the video 8 record. 9 (WHEREUPON, a recess was had 10 from 3:52 to 4:02 p.m.) 11 THE VIDEOGRAPHER: The time is 4:02 p.m. This 12 is the beginning of Tape 3 and we are back on the 13 video record. 14 MR. COMBS: Adam, that's all the questions I 15 have for Dr. Elser at this time. I might have some 16 follow-up after you're done. 17 MR. SLATER: Splendid. Okay. 18 Dr. Elser -- are we back on, by the way? 19 MR. COMBS: Yes. 20 THE WITNESS: We're on. 21 FURTHER EXAMINATION 22 BY MR. SLATER: 23 Q. Dr. Elser, the version of the IFU you 24 have in front of you, do you know when that IFU was 25 in effect?</p>	<p>1 Q. You said that one of your bases for your 2 opinions about the IFU is based on speaking to 3 doctors about the IFU. Remember you said that? 4 A. Yes. 5 Q. Can you tell me who you spoke to and 6 when you spoke to them and what -- so that I know 7 what you're relying on? 8 A. Well, it was mostly when we did cadaver 9 courses and preceptor courses and the physicians 10 would always have a lot of questions for us in 11 between or after or at the cadavers. We would talk 12 about what was in the IFU or what points were 13 important and -- 14 Q. Nothing that I could be able to -- 15 nothing you could tell me so I could verify who you 16 spoke to and when you spoke to them and what the 17 content was, right? 18 A. No. 19 Q. And, of course, you don't know what was 20 in their minds beyond what you discussed. So, for 21 example, a doctor may have asked you questions 22 about the procedure and you may have discussed the 23 IFU in that context and the doctor could have on 24 his or her own read all of the warnings and adverse 25 events and relied on that without discussing that</p>
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<p>1 A. The date on it says 11/07. 2 Q. Does that mean anything to you in terms 3 of when it was in effect? Do you know the point in 4 time when it went into use and when it went out of 5 use? 6 A. No, I don't. 7 Q. Do you know whether you ever saw that 8 IFU before you were retained to look at it in this 9 litigation? 10 A. I don't know and I thought about this 11 earlier. When you initially learn a procedure, you 12 get the IFU and you look at it, you examine it and 13 you may pull it out if you haven't done the 14 procedure in a while. 15 But I can't say how a surgeon would ever 16 know once an IFU changes to think to look for a 17 newer version if they're still doing the procedure. 18 So, that's one reason we would not look to the IFU 19 for updated list of complications. 20 Q. Are you aware of the fact that a medical 21 device company can tell the doctors that they are 22 working with that the IFU has been updated and 23 suggest that they take a look at the parts that 24 have been updated? 25 A. Oh, absolutely.</p>	<p>1 with you. That could have happened many times, 2 right? 3 A. That could have. 4 Q. The IFU does not say anything about the 5 level of knowledge a surgeon would need to have or 6 be expected to have regarding the Prolift 7 procedure. It doesn't say that, right? 8 MR. COMBS: Object to the form. 9 BY THE WITNESS: 10 A. It says they should be familiar with 11 pelvic reconstructive surgery and placement of 12 non-absorbable mesh. 13 BY MR. SLATER: 14 Q. And how is "familiar with" defined in 15 the IFU? Is there any definition offered there? 16 A. Not that I saw. 17 Q. In fact, some doctors could think that 18 if they had done three procedures with mesh where 19 they sewed it in as part of a colporrhaphy that 20 they were familiar with mesh procedures, right? 21 A. Oh, yes. There is a lot left up to 22 surgeon judgment. 23 Q. So, "familiar with" really is a word 24 that doesn't really mean anything unless you ask 25 the person who is reading it what they think it</p>

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<p>1 means, right?</p> <p>2 MR. COMBS: Object to the form.</p> <p>3 BY THE WITNESS:</p> <p>4 A. It's up to the surgeon to know if they</p> <p>5 have sufficient knowledge of a new procedure to</p> <p>6 undertake it in a patient.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. And sufficient knowledge, that's not</p> <p>9 something that could be defined in any objective</p> <p>10 way, right?</p> <p>11 A. Right.</p> <p>12 Q. There is nowhere in the IFU where it's</p> <p>13 disclosed that Prolift complications could lead to</p> <p>14 multiple operations and despite the multiple</p> <p>15 operations, the woman would not get better and</p> <p>16 could actually be left with permanent disabling</p> <p>17 pain, those words and words to that effect do not</p> <p>18 appear in the IFU, correct?</p> <p>19 A. I did not see that in the IFU.</p> <p>20 Q. That is a risk with the Prolift,</p> <p>21 correct?</p> <p>22 A. It's a risk with the Prolift and with</p> <p>23 other pelvic surgeries.</p> <p>24 MR. SLATER: Move to strike from "and"</p> <p>25 forward.</p>	<p>1 Q. Well, in terms of your opinions about</p> <p>2 whether or not Ms. Bellew had pelvic floor myalgia</p> <p>3 before the Prolift surgery, there is no objective</p> <p>4 evidence in any medical record indicating that,</p> <p>5 correct?</p> <p>6 A. Correct.</p> <p>7 Q. I'm correct, right?</p> <p>8 A. Yes. Oh, I said yes. Sorry.</p> <p>9 Q. So, any opinion you would offer that</p> <p>10 Ms. Bellew had pelvic floor myalgia before the</p> <p>11 Prolift surgery would be speculative since there is</p> <p>12 no objective evidence of it, correct?</p> <p>13 A. Yes.</p> <p>14 Q. You talked about the hysterectomy a</p> <p>15 little bit.</p> <p>16 A. Yes.</p> <p>17 Q. I don't need to ask about that. Let's</p> <p>18 see what else I can do.</p> <p>19 Did you see pictures that were taken of</p> <p>20 any of the mesh that was removed from Ms. Bellew's</p> <p>21 body?</p> <p>22 A. No.</p> <p>23 Q. You did not see any of the expert</p> <p>24 reports with regard to the pathology?</p> <p>25 A. No.</p>
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<p>1 BY MR. SLATER:</p> <p>2 Q. Did Ms. Bellew's records indicate that</p> <p>3 she had a chronic cough?</p> <p>4 A. No. I'm surmising that she's likely to</p> <p>5 have a chronic cough since she is a smoker and she</p> <p>6 has lung disease and has been placed on oxygen.</p> <p>7 Q. You're speculating that Ms. Bellew had a</p> <p>8 chronic cough, correct?</p> <p>9 A. Yes, because I take care of a lot of</p> <p>10 smokers.</p> <p>11 MR. SLATER: Move to strike after "yes."</p> <p>12 BY MR. SLATER:</p> <p>13 Q. In terms of your testimony about whether</p> <p>14 or not Ms. Bellew had pelvic floor myalgia before</p> <p>15 the Prolift surgery, first of all, there is no</p> <p>16 medical record documenting that that condition</p> <p>17 existed, correct?</p> <p>18 A. Correct.</p> <p>19 Q. You're speculating that it may have</p> <p>20 existed but you have no proof, correct?</p> <p>21 MR. COMBS: Object to the form.</p> <p>22 BY THE WITNESS:</p> <p>23 A. I'm speculating that it was likely to</p> <p>24 have been there, yes.</p> <p>25 BY MR. SLATER:</p>	<p>1 Q. And the pathologic analysis of the</p> <p>2 removed mesh or tissue, right?</p> <p>3 A. Correct.</p> <p>4 Q. Whatever Ms. Bellew's condition was</p> <p>5 before the Prolift and whatever other conditions</p> <p>6 she may have had, that did not impact on the fact</p> <p>7 that she ended up with mesh contraction, hardened</p> <p>8 mesh, pain from that hardened mesh, dyspareunia</p> <p>9 from that hardened mesh and the need for three</p> <p>10 operations to remove that mesh, correct?</p> <p>11 MR. COMBS: Object to the form.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Potentially. So, because I'm making the</p> <p>14 assumption that she likely had myofascial</p> <p>15 hypertonicity, that can cause a tight mesh band</p> <p>16 that may not be true hardening like a calcification</p> <p>17 of the mesh but tension on the mesh arm that would</p> <p>18 be tender to palpation.</p> <p>19 Q. If she had myofascial pain before the</p> <p>20 Prolift, that would be a contributing factor; but</p> <p>21 the Prolift itself being in the body and its</p> <p>22 interaction with the body would be the primary</p> <p>23 cause of those conditions and those problems,</p> <p>24 right?</p> <p>25 A. Well, again, if I could explain a little</p>

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<p style="text-align: right;">Page 210</p> <p>1 further. If you palpate a mesh arm and it feels 2 taut, you can say there's fibrosis contraction of 3 tissue grown around the mesh arm or that the muscle 4 that's attached at the end of the mesh is tight and 5 pulling on the mesh arm to make it feel tight on 6 exam and if I relieve that tension or cut the arm, 7 I'm just breaking that cycle. They are no longer 8 connected. 9 So, yes, she had tension where the mesh 10 arm was; but if the muscle was of normal tone, it 11 might no longer feel hard and taut. 12 Q. Well, in this case Dr. DeHasse actually 13 confirmed that she looked at the mesh and could see 14 that there was fibrotic scar plates actually on the 15 mesh and contracting the mesh, correct? 16 MR. COMBS: Object to the form. 17 BY MR. SLATER: 18 Q. She confirmed she observed that, 19 correct? 20 A. Yes, but as a surgeon who has taken out 21 mesh arms, I don't know what that means. 22 Q. Well, assuming Dr. DeHasse saw the 23 fibrotic tissue encrusted across the mesh, 24 that's -- you have no reason to dispute that, do 25 you?</p>	<p style="text-align: right;">Page 212</p> <p>1 MR. SLATER: Objection. 2 BY THE WITNESS: 3 A. Yes. 4 BY MR. COMBS: 5 Q. Mr. Slater asked you about no objective 6 evidence in any medical record of the fact that 7 Ms. Bellew had pelvic floor myalgia prior to the 8 Prolift implant. But in fact there would be 9 objective evidence of all the risk factors that you 10 described related to the potential for her having 11 pelvic floor myalgia, isn't there? 12 A. Yes. 13 MR. SLATER: Objection. 14 MR. COMBS: That's all the questions I have, 15 Adam. Anything else? 16 MR. SLATER: Nope. 17 MR. COMBS: Okay. 18 MR. SLATER: See you at the next one, 19 Dr. Elser. 20 THE VIDEOGRAPHER: Okay. The time is 4:12 21 p.m. This is the end of Tape 3 and it also 22 concludes the deposition of Dr. Denise Elser and we 23 are off video record. 24 (Time Noted: 4:12 p.m.) 25 FURTHER DEPONENT SAITH NAUGHT.</p>
<p style="text-align: right;">Page 211</p> <p>1 MR. COMBS: Object to form. 2 BY THE WITNESS: 3 A. Well, there's scar tissue that's laid 4 down, fibrosis that may not be under undue tension 5 that wouldn't necessarily be painful to the 6 patient. 7 So, I'm saying it's the combination of 8 the mesh band being there and tension that may be 9 causing the pain and tension she is feeling. 10 BY MR. SLATER: 11 Q. You have no evidence from any medical 12 record or document that there was pelvic floor 13 myalgia causing a tension band before the Prolift 14 was put in or during the time when it was being 15 treated by Dr. DeHasse, correct? 16 A. Correct. 17 MR. SLATER: I have no other questions. 18 MR. COMBS: Very, very brief. 19 FURTHER EXAMINATION 20 BY MR. COMBS: 21 Q. Dr. Elser, Mr. Slater asked you about a 22 risk of multiple operations to treat complications 23 from Prolift. In fact, the risk of multiple 24 operations to treat complications would be a risk 25 of any pelvic floor surgery, wouldn't it?</p>	<p style="text-align: right;">Page 213</p> <p>1 I, CORINNE T. MARUT, C.S.R. No. 84-1968, 2 Registered Professional Reporter and Certified 3 Shorthand Reporter, do hereby certify: 4 That previous to the commencement of the 5 examination of the witness, the witness was duly 6 sworn to testify the whole truth concerning the 7 matters herein; 8 That the foregoing deposition transcript 9 was reported stenographically by me, was thereafter 10 reduced to typewriting under my personal direction 11 and constitutes a true record of the testimony 12 given and the proceedings had; 13 That the said deposition was taken 14 before me at the time and place specified; 15 That the reading and signing by the 16 witness of the deposition transcript was agreed 17 upon as stated herein; 18 That I am not a relative or employee of 19 attorney or counsel, nor a relative or employee of 20 such attorney or counsel for any of the parties 21 hereto, nor interested directly or indirectly in 22 the outcome of this action. 23 It was requested before completion of 24 the deposition that the witness, DENISE M. ELSE, M.D., 25 have the opportunity to read and sign the 26 deposition transcript. 27 28 CORINNE T. MARUT, Certified Reporter 29 30 (The foregoing certification of this 31 transcript does not apply to any 32 reproduction of the same by any means, unless under 33 the direct control and/or supervision of the 34 certifying reporter.) 35</p>

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1 INSTRUCTIONS TO WITNESS	1 ACKNOWLEDGMENT OF DEPONENT
2	2
3 Please read your deposition	3 I, _____, do
4 over carefully and make any necessary	4 hereby certify that I have read the
5 corrections. You should state the reason	5 foregoing pages, and that the same
6 in the appropriate space on the errata	6 is a correct transcription of the answers
7 sheet for any corrections that are made.	7 given by me to the questions therein
8 After doing so, please sign	8 propounded, except for the corrections or
9 the errata sheet and date it. It will be	9 changes in form or substance, if any,
10 attached to your deposition.	10 noted in the attached Errata Sheet.
11 It is imperative that you	11 _____
12 return the original errata sheet to the	12 DENISE M. ELSER, M.D. DATE
13 deposing attorney within thirty (30) days	13
14 of receipt of the deposition transcript	14
15 by you. If you fail to do so, the	15 Subscribed and sworn
16 deposition transcript may be deemed to be	16 to before me this
17 accurate and may be used in court.	17 _____ day of _____, 20____.
18	18 My commission expires: _____
19	19 _____
20	20 Notary Public
21	21
22	22
23	23
24	24
25	25

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2 E R R A T A	2 PAGE LINE
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5 _____	5
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24 REASON: _____	24
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